**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

**FORM 10-K**

(Mark One)
☑ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

**For the fiscal year ended December 31, 2018**

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

**Commission file number: 001-35285**

**Vaxart, Inc.**
(Exact Name of Registrant as Specified in its Charter)

| **Delaware** | **59-1212264** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (IRS Employer Identification No.) |
| **290 Utah Ave., Suite 200, South San Francisco, CA** | **94080** |
| (Address of principal executive offices) | (Zip Code) |

**(650) 550-3500**
(Registrant's telephone number, including area code)

**Securities registered pursuant to Section 12(b) of the Act:**

| Title of Each Class: | Name of Each Exchange on Which Registered: |
|---|---|
| **Common Stock, par value $0.10 per share** | **The Nasdaq Capital Market** |

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers in response to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

| | |
|---|---|
| Large accelerated filer ☐ | Accelerated filer ☐ |
| Non-accelerated filer ☑ | Smaller reporting company ☑ |
| | Emerging growth company ☐ |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the Registrant's common stock held by non-affiliates of the Registrant as of the last business day of the Registrant's most recently completed second fiscal quarter, June 30, 2018, based on the last reported sales price of the Registrant's common stock of $3.03 per share was $12,181,506.

As of February 4, 2019, the registrant had a total of 7,141,189 shares of common stock issued and outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

# TABLE OF CONTENTS

## FORWARD-LOOKING STATEMENTS

*This Annual Report on Form 10-K for the year ended December 31, 2018, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections, concerning our business, operations, and financial performance and condition as well as our plans, objectives, and expectations for business operations and financial performance and condition. Any statements contained herein that are not of historical facts may be deemed to be forward-looking statements. You can identify these statements by words such as "anticipate," "assume," "believe," "could," "estimate," "expect," "intend," "may," "plan," "should," "will," "would," and other similar expressions that are predictions of or indicate future events and future trends. These forward-looking statements are based on current expectations, estimates, forecasts, and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties, and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Annual Report on Form 10-K may turn out to be inaccurate. Factors that could materially affect our business operations and financial performance and condition include, but are not limited to, those risks and uncertainties described herein under "Item 1A - Risk Factors." You are urged to consider these factors carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are based on information available to us as of the filing date of this Annual Report on Form 10-K. Unless required by law, we do not intend to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the Securities and Exchange Commission, or the SEC, after the date of this Annual Report on Form 10-K.*

*In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.*

This Annual Report on also contains market data related to our business and industry. These market data include projections that are based on a number of assumptions. If these assumptions turn out to be incorrect, actual results may differ from the projections based on these assumptions. As a result, our markets may not grow at the rates projected by these data, or at all. The failure of these markets to grow at these projected rates may harm on our business, results of operations, financial condition and the market price of our common stock.

# PART I

## Item 1. Business

### Overview

Vaxart Biosciences, Inc. was originally incorporated in California in March 2004, under the name West Coast Biologicals, Inc. and changed its name to Vaxart, Inc., or Private Vaxart, in July 2007, and reincorporated in the state of Delaware.

On February 13, 2018, Private Vaxart completed a reverse merger, or the Merger, with Aviragen Therapeutics, Inc., or Aviragen, pursuant to which Private Vaxart survived as a wholly owned subsidiary of Aviragen. Under the terms of the Merger, Aviragen changed its name to Vaxart, Inc. and Private Vaxart changed its name to Vaxart Biosciences, Inc. Unless otherwise indicated, all references to "Vaxart," "we," "us," "our" or the "Company" in this Annual Report on Form 10-K mean Vaxart, Inc., the combined company.

We are a clinical-stage biotechnology company focused on the development of oral recombinant vaccines based on our proprietary oral vaccine platform. Our oral vaccines are designed to generate broad and durable immune responses that protect against a wide range of infectious diseases and may be useful for the treatment of chronic viral infections and cancer. Our vaccines are administered using a convenient room temperature-stable tablet, rather than by injection.

We are developing prophylactic vaccine candidates that target a range of infectious diseases. These include norovirus, a widespread cause of acute gastro-intestinal enteritis, for which two Phase 1 human studies have been completed; seasonal influenza, for which our vaccine protected patients in a recent Phase 2 challenge study; and respiratory syncytial virus, or RSV, a common cause of respiratory tract infections. In addition, we are developing our first therapeutic immune-oncology vaccine targeting cervical cancer and dysplasia caused by human papillomavirus, or HPV.

Vaccines have been essential in eradicating or significantly reducing multiple devastating infectious diseases, including polio, smallpox, mumps, measles, diphtheria, hepatitis B, influenza, human papillomavirus and several others. According to a recent MarketsandMarkets research report "Vaccines Market - Global Forecast to 2023", the global market for vaccines is expected to reach $50.42 billion by 2023 from $36.45 billion in 2018, at a compound annual growth rate of 6.7%.

We believe our oral tablet vaccine candidates offer several important advantages:

First, they are designed to generate broad and durable immune responses, including systemic, mucosal and T cell responses, which may enhance protection against certain infectious diseases, such as influenza, norovirus and RSV, and may have potential clinical benefit for certain cancers and chronic viral infections, such as those caused by HPV.

Second, our tablet vaccine candidates are designed to provide a more efficient and convenient method of administration, enhance patient acceptance and reduce distribution bottlenecks, which we believe will improve the effectiveness of vaccination campaigns. For example, according to the U.S. Centers for Disease Control and Prevention, or CDC, in the 2017/2018 seasonal influenza season, only approximately 42% of the U.S. population was vaccinated against influenza, with particularly low vaccination rates among adults between ages 18 and 49.

Finally, we believe that utilizing our recombinant methods and production process will allow us to manufacture vaccines at scale more efficiently and within shorter time frames than conventional vaccines manufactured using traditional methods.

### Our Product Pipeline

We are developing the following tablet vaccine candidates, which are all based on our proprietary platform:

- ***Norovirus Vaccine.*** We are developing an oral tablet vaccine for norovirus, a leading cause of acute gastroenteritis in the United States and Europe. Because norovirus infects the small intestine, we believe that our vaccine, which is designed to produce mucosal antibodies locally in the intestine in addition to systemic antibodies in the blood, will better protect against norovirus infection than an injectable vaccine. Clinical evidence that vaccines based on our platform technology can protect against infection is described under "Clinical Trial Update" in the "Seasonal Influenza Vaccine" section below.

  Norovirus is the leading cause of vomiting and diarrhea from acute gastroenteritis among people of all ages in the United States. Each year, on average, norovirus causes 19 to 21 million cases of acute gastroenteritis and contributes to 56,000 to 71,000 hospitalizations and 570 to 800 deaths, mostly among young children and older adults. Typical symptoms include dehydration, vomiting, diarrhea with abdominal cramps, and nausea. In a study conducted by Pittsburg School of Medicine in 2012, the total economic burden of norovirus in the United States was estimated at $5.5 billion. In a more recent study by CDC and Johns Hopkins University, the global economic impact of norovirus disease was estimated at $60 billion, $34 billion of which occurred in high income countries including the United States, Europe and Japan. Virtually all norovirus disease is caused by norovirus GI and GII genotypes, and we are developing a bivalent vaccine designed to protect against both.

*Clinical Trial Update*. We have completed two Phase 1 clinical trials with our monovalent oral tablet vaccine for the GI.1 norovirus strain. The vaccine was well-tolerated and generated broad systemic and mucosal immune responses. In the clinical Phase 1b dose optimization study in healthy adults in which we evaluated four different dosing regimens, all vaccine recipients (100%) in the high dose group responded as measured by a significant increase in norovirus-specific B cells of both IgA and IgG subtypes. In the same group, there was at least a two-fold increase of norovirus-specific antibody titers in serum in more than 90% of recipients.

We are preparing for two norovirus clinical trials, a bivalent Phase 1 study designed to assess safety and immunogenicity of our norovirus GI.1 and GII.4 vaccines administered concurrently, and a monovalent Phase 2 challenge study designed to assess the protective efficacy of our norovirus GI.1 vaccine against live norovirus GI.1 challenge in humans. The Phase 1 bivalent study and the Phase 2 challenge study will both be conducted under an open IND. Clinical protocols for both studies have been submitted to the FDA. In preparation for the Phase 2 challenge study, we have conducted a virus titration study to help determine the appropriate quantity of the norovirus GI.1 virus to be used to challenge patients in the study.

The bivalent study is conducted using both the norovirus GI.1 and GII.4 vaccines. The challenge study is conducted using only the norovirus GI.1 vaccine. As announced in November 2018, the norovirus GI.1 vaccine tablets that we manufactured in 2018 failed release testing, causing both studies that were scheduled to begin before the end of 2018 to be delayed. Since then, we have manufactured two new lots of bulk GI.1 vaccine that are scheduled to be processed and tableted in the coming weeks. If processing and tableting is successful and the vaccine passes all required release testing, the norovirus GI.1 vaccine tablets are expected to become available for the currently planned clinical trials during the second quarter of 2019. The norovirus GII.4 vaccine tablets we manufactured in 2018 have passed all required release testing and are available for use in our clinical trials, subject to final review of the Certificate of Analysis by the FDA. For more information on our manufacturing process, capabilities and strategy, please see the paragraph "Manufacturing" in this business section below.

- ***Seasonal Influenza Vaccine.*** Influenza is a major cause of morbidity and mortality in the U.S. and worldwide and, according to the CDC, only 42% of eligible U.S. citizens were vaccinated in 2017/2018, with particularly low vaccination rates among adults between ages 18 and 49. We believe our oral tablet vaccine has the potential to improve the protective efficacy of currently available influenza vaccines and increase flu vaccination rates.

  Influenza is one of the most common global infectious diseases, causing mild to life-threatening illness and even death. It is estimated that at least 350 million cases of seasonal influenza occur annually worldwide, of which three to five million cases are considered severe, causing 290,000 to 650,000 deaths per year globally. During the most recent flu season 2017 – 2018, there were 79,400 flu related deaths in the U.S. alone, according to the CDC. Very young children and the elderly are at the greatest risk. In the United States, between 5% and 20% of the population contracts influenza, 226,000 people are hospitalized with complications of influenza, and between 3,000 and 49,000 people die from influenza and its complications each year, with up to 90% of the influenza-related deaths occurring in adults older than 65. The total economic burden of seasonal influenza has been estimated to be $87.1 billion, including medical costs which average $10.4 billion annually, while lost earnings due to illness and loss of life amount to $16.3 billion annually.

  We believe our tablet vaccine candidate has the potential to address many of the limitations of current injectable egg-based influenza vaccines, because: our tablet vaccine candidates are designed to create broad and durable immune responses, which may provide more effective immunity and protect against additional strain variants; our vaccine is delivered as a room temperature-stable tablet, which should provide a more convenient method of administration to enhance patient acceptance, and should simplify distribution and administration; and, by using recombinant methods, we believe our tablet vaccine may be manufactured more rapidly than vaccines manufactured using egg-based methods and should eliminate the risk of allergic reactions to egg protein.

  *Clinical Trial Update*. In September 2018, we completed a $15.7 million contract with the U.S. Government through the Office of Biomedical Advanced Research and Development Authority, or BARDA, under which a Phase 2 challenge study of our H1N1 flu vaccine candidate was conducted. Previously, we had announced that, in healthy volunteers immunized and then experimentally infected with H1 influenza, our H1 influenza oral tablet vaccine reduced clinical disease by 39% relative to placebo, a result that was superior to that of Fluzone, the market-leading injectable quadrivalent influenza vaccine, which reduced clinical disease by only 27%. Our tablet vaccine also showed a favorable safety profile, indistinguishable from placebo. On October 4, 2018, we presented data from the study demonstrating that our vaccine elicited a significant expansion of mucosal homing receptor plasmablasts to approximately 60% of all activated B cells, while Fluzone only maintained baseline levels of 20%. We believe plasmablasts are a key indicator of a protective mucosal immune response and a unique feature of our vaccines. This data also provided evidence that our vaccines protect through mucosal immunity, the first line of defense against mucosal infections such as flu, norovirus, RSV and others, a potential key advantage over injectable vaccines for these indications.

At this time, we aim to finance development and commercialization of our seasonal quadrivalent influenza oral tablet vaccine through third-party collaboration and licensing arrangements, and/or non-dilutive funding. In the future, we may also consider equity offerings and/or debt financings to fund the program.

- ***HPV Therapeutic Vaccine.*** Our first therapeutic oral vaccine candidate targets HPV-16 and HPV-18, the two strains responsible for 70% of cervical cancers and precancerous cervical dysplasia.

  Cervical cancer is the fourth most common cancer in women worldwide and in the United States with about 13,000 new cases diagnosed annually in the United States according to the National Cervical Cancer Coalition.

  We have tested our HPV-16 vaccine candidate in two different HPV-16 solid tumor models in mice. The vaccine elicited T cell responses and promoted migration of the activated T cells into the tumors, leading to tumor cell killing. Mice that received our HPV-16 vaccine showed a significant reduction in volume of their established tumors.

  In October 2018, we filed a pre-IND meeting request for our HPV therapeutic vaccines, VXA-HPV16.1 and VXA-HPV18.1, with the FDA, and we subsequently submitted a pre-IND briefing package. We received feedback from the FDA in January 2019 providing guidance for the IND we plan to submit. Based on this feedback, we expect to be able to file an IND for this product candidate in the course of 2019.

- ***RSV Vaccine.*** RSV is a major respiratory pathogen with a significant burden of disease in the very young and in the elderly.

  Based on the positive results of our cotton rat study, we believe our proprietary oral vaccine platform is the optimal vaccine delivery system for RSV, offering significant advantages over injectable vaccines. We aim to develop a tablet RSV vaccine by licensing one or more RSV protein antigens that have demonstrated protection against RSV infection in clinical studies, or by partnering with a third party with RSV antigens that can be delivered with our platform.

**Additional Objectives**

- ***Develop Other Tablet Vaccine Candidates Based On Our Proprietary Platform.*** Our technology platform employs a modular approach using the Ad5 vector-adjuvant construct with disease-specific antigens and can be used to create new tablet vaccine candidates for a wide range of infectious diseases. We may consider exploring additional infectious diseases including RSV, Chikungunya, Hepatitis B and Herpes Simplex Virus 2, or HSV-2. In addition, we intend to leverage our vaccine formulation expertise to develop oral formulations suitable for pediatric populations.
- ***Further Strengthen Our Intellectual Property Portfolio***. We intend to continue to strengthen our patent portfolio by filing and prosecuting current and future patent applications in the United States and international jurisdictions. In addition, we have established in-house formulation and tableting capabilities which we believe will allow us to further improve and optimize our proprietary techniques and know-how.
- ***Maximize the Commercial Value of Our Tablet Vaccine Candidates*** . We believe that we own worldwide rights for the research, development, manufacturing, marketing and commercialization of our tablet vaccine candidates. As we further develop our product candidates, we may seek partners to maximize the commercial opportunity of such tablet vaccine candidates.

**Anti-Virals**

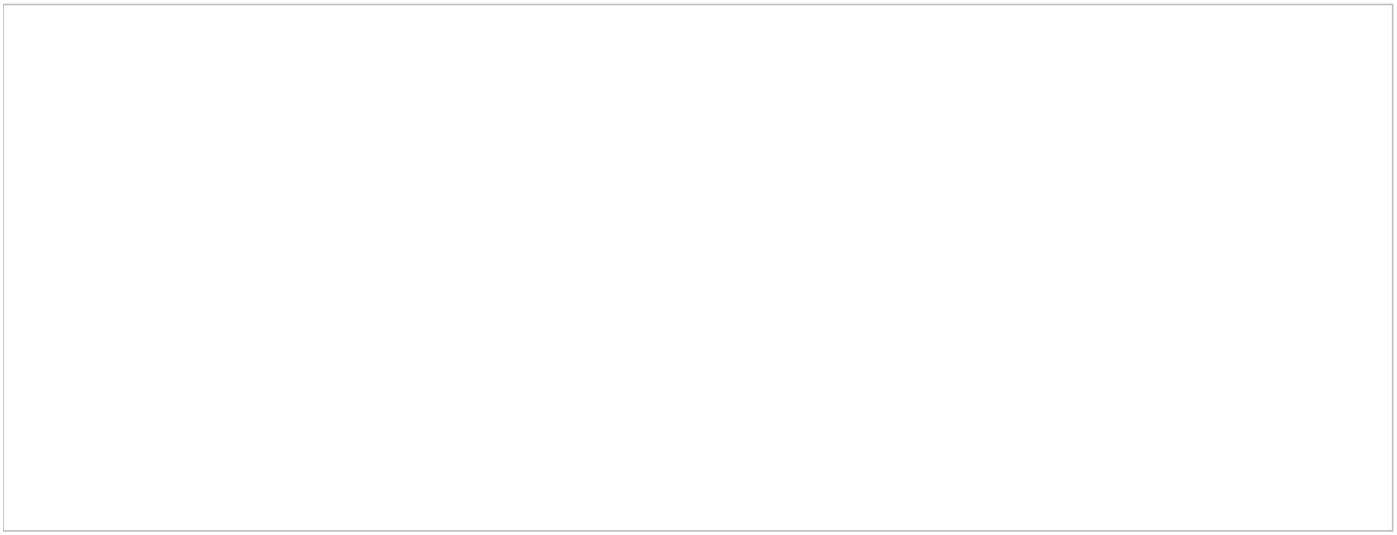
- Through our merger with Aviragen Therapeutics, Inc., or Aviragen, we acquired two royalty earning products, Relenza and Inavir, and three Phase 2 clinical stage antiviral compounds.

- Relenza and Inavir are antivirals for the treatment of influenza that are marketed by GSK and Daiichi Sankyo, respectively. We earn royalties on the net sales of Relenza and Inavir in Japan. Sales of Relenza and Inavir vary significantly from one year to the next, depending on the intensity of the flu season and competition from other antivirals such as Tamiflu. Importantly, on February 23, 2018, Xofluza, a new drug to treat influenza developed by Shionogi, was approved in Japan. The drug may gain significant market share, substantially reducing sales of Inavir.

- The three Phase 2 antiviral compounds obtained through the merger with Aviragen are: 1) BTA074, or teslexivir, an antiviral treatment for condyloma caused by human papillomavirus types 6 & 11; 2) vapendavir, a capsid inhibitor for the prevention or treatment of rhinovirus upper respiratory infections; and 3) BTA585, or enzaplatovir, a fusion protein inhibitor for the treatment of RSV infections. We have discontinued all three programs.

**Our Pipeline**

**Fig. 1.** The following table outlines the status of our oral vaccine development programs and our two marketed products:



**Our Tablet Vaccine Platform**

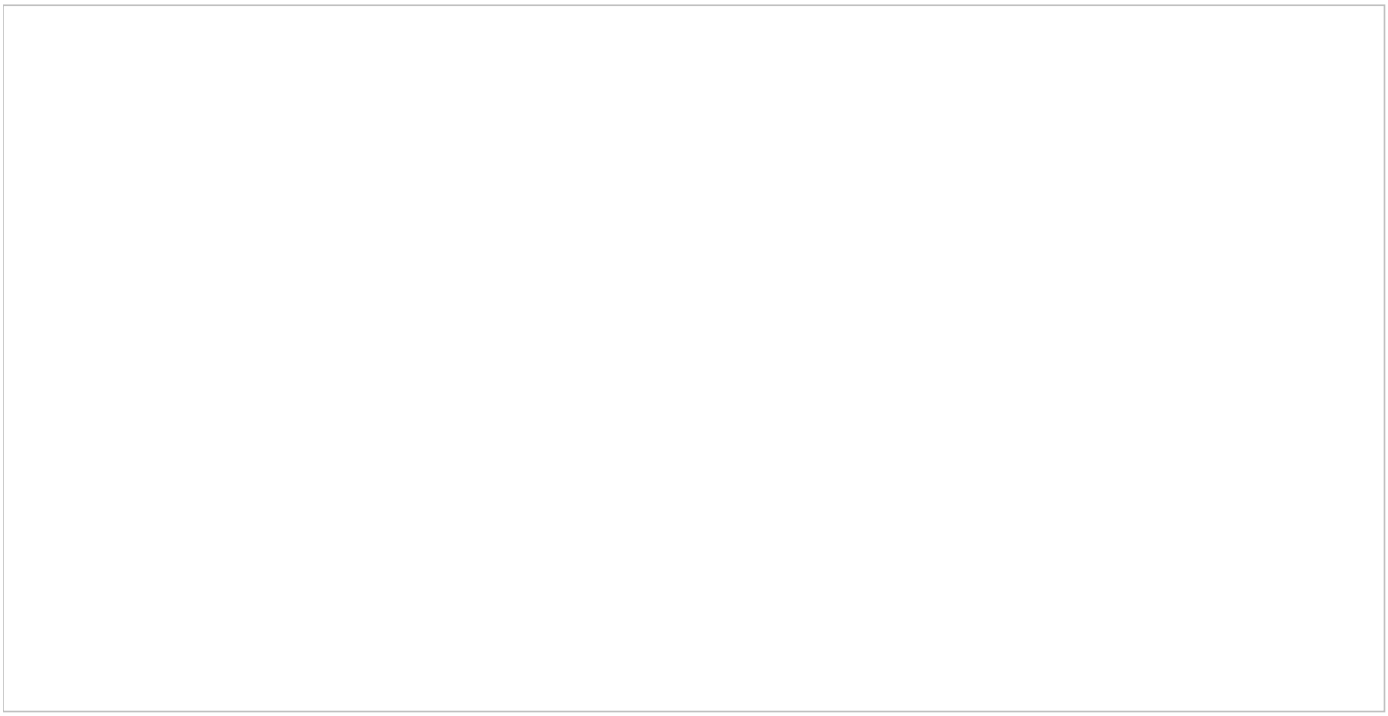
Vaccines based on our oral adjuvant-vector platform are designed to generate broad local and systemic immune responses, which may offer important advantages in addressing a wide range of infectious diseases.

***Platform Components***

Our platform technology employs a vector-based approach and consists of the following components:

- A vector, which is a virus used as a carrier to deliver DNA coding for vaccine antigens and an adjuvant selected to activate the immune system of the gut. Specifically, we use non-replicating adenovirus type 5, or Ad5, which delivers the DNA for both the antigen and adjuvant to the cells of the small intestine, where both the antigen and adjuvant are co-expressed.
- A protein antigen, which is a viral or bacterial protein that stimulates an immune response to the selected pathogen. We use a different antigen for each of our current clinical vaccine candidates.
- An adjuvant, which is a substance that enhances the immune-stimulating properties of the vaccine. We use a Toll-like receptor 3, or TLR3, agonist, which was selected specifically for its ability to activate the immune system of the gut.
- Our proprietary enteric-coated tablet which is designed to deliver the Ad5 vector to the small intestine.

**Fig. 2.** Our VAAST Platform.



*Caption. Vector-Adjuvant-Antigen Standardized Technology Platform*

***Our Platform.*** *Combination of the vector-based delivery system, with antigen and adjuvant expressed by the vector.*

***Adenovirus 5 Vector***

Ad5 is an extensively studied and well-characterized vector. Over 200 clinical trials conducted by others have used Ad5 for a wide range of applications, and we believe that using the same adenovirus in our tablet vaccine candidates will reduce regulatory risk, given that it is known to regulatory authorities.

***Recombinant Antigen***

Our vector contains cloning space where DNA encoding for any recombinant antigen can be inserted. In the vaccine programs pursued to date, we have chosen recombinant antigens that are known to be key targets of the immune system with the ability to generate protection against the corresponding pathogen. The Ad5 vector-adjuvant gene cassette allows for a modular approach.

***Adjuvant***

We use a short section of double-stranded RNA, or dsRNA, as an adjuvant to enhance the immunogenicity of our tablet vaccine candidates. dsRNA is a Toll Like Receptor 3 (TLR3) agonist and is recognized by the innate immune system as a signal that an undesired viral replication is ongoing, triggering it to mount an immune response in defense. dsRNA is one of the few signals available for use in the intestine as the natural large reservoir of bacteria (the "microbiome") makes it difficult to use bacteria- related signals. We chose this adjuvant because of its ability to complement the non-replicating adenovirus when administered orally, and because very few pathways of immune system recognition signals occur in the small intestine. Importantly, our adjuvant is expressed within a cell, not provided as a separate component, resulting in a more localized response when compared with adjuvants contained in injectable vaccines.

***Enteric-Coated Tablet***

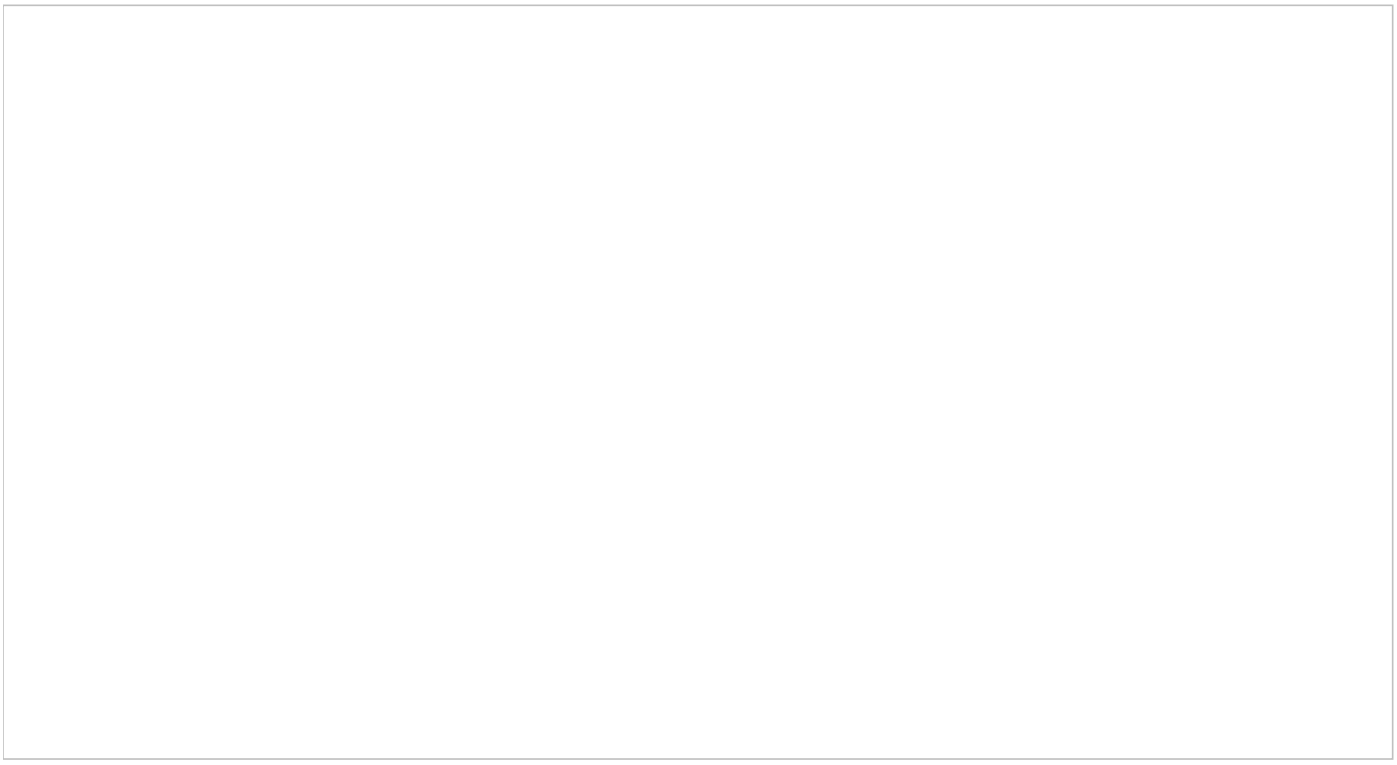
While tablets are typically used to deliver small molecules to the intestine, we have designed our tablets to deliver the much larger adenovirus particles. We hold intellectual property related to the composition and formulation of our tablet vaccine candidates. Our tablet manufacturing does not require sterile fill and finish processing, such as for injectables, but rather uses standard tableting equipment.

***How Our Tablet Vaccine Candidates Work***

Our tablets are designed to deliver vaccines to the small intestine. The tablets are covered with a protective coating that remains intact in the low pH environment of the stomach and protects the active ingredient contained in the tablet core from the acidic environment in the stomach. The coating is designed to dissolve in the neutral pH environment of the small intestine which we are targeting to generate an optimal immune response. Once the coating has dissolved, the tablets disintegrate, and the vaccine is released into the small intestine where it can reach and enter the mucosal cells lining the intestine. Once inside the mucosal cells, the antigen protein and adjuvant are expressed, or manufactured, by the cells. The adjuvant is molecular in nature and always produced within the exact same intestinal cells that also produce the antigen. Importantly, unlike current recombinant vaccines that are manufactured in insect cells or yeast which may introduce subtle structural changes to the protein antigen, the production of antigens delivered using our approach is identical to that of the actual pathogen when it invades the mucosa. In addition, we believe that delivering the replication incompetent Ad5-vectored vaccine

via tablet directly to the gut avoids neutralization by blood or muscle tissue-based immune cells, an advantage over injected vector-based vaccines.

**Fig. 3.** Our Oral Recombinant Vaccine Platform.



*Caption. 1. Enteric-coated tablet is administered. The tablet coating protects the active ingredient from stomach acid degradation. 2. When the tablet reaches the small intestine, it releases the active ingredient, the viral vector, that can then transfect the epithelial cells in the mucosal epithelium and deliver the genes for the two payloads (antigen and adjuvant). 3. Expression of the antigen and adjuvant in the epithelial cells then leads to the TLR3 signaling cascade that can activate B and T cells.*

Immune cells come in contact with proteins, and if the protein elicits an immune recognition signal, the immune cell becomes activated. This eventually leads to an immune response, producing either memory cells or large quantities of antibodies that bind to a key antigen. The expressed antigen and adjuvant of its platform, like other vaccines, cause induction of B and T cells specific for the antigen. Induction is believed to begin when an immature dendritic cell (specialized immune cell) absorbs an epithelial cell expressing both the antigen and adjuvant that were delivered by the Ad5 vector. Upon induction, dendritic cells migrate to the regional lymph nodes where they interact with recirculating naive B and T cells. The dendritic cell presents pieces of the antigen on its surface to stimulate T cells, and some of the antigen drains into the lymph node to stimulate B cells. Upon recognizing its specific antigen, small B or T cells stop migrating and enlarge. These then multiply in a clonal fashion and eventually recirculate to the tissues. B cells secrete antibodies that recognize the antigen and T cells find cells that have antigen presented on their surface and either kill the presenting cell or stimulate a local inflammatory response. A successful vaccination occurs if the B cells and T cells can form either memory cells (cells specialized to respond quickly to the protective antigen upon subsequent exposure) or enough antibody to a key antigen is made in large quantity to block infection.

***The Significance of Mucosal Immunity and T Cell Responses***

The immune system has developed defenses against pathogens by creating a special class of immune effectors, such as mucosal antibodies that are directed to wet surfaces and killer T cells that can kill pathogen infected cells. Most vaccines available today have been developed primarily to elicit blood circulating, or systemic B cell responses. However, there remain many infections, such as norovirus and RSV for which no vaccines exist. These and other pathogens may need greater immune responses outside of serum antibodies. Organisms that cause these infections largely evade the antibody immune response generated by serum antibodies in the blood because the pathogenic organism can pass through cells that line the open, mucosal membranes without coming into direct contact with blood. Alternatively, the serum antibodies are unable to penetrate into the cells infected by the pathogen.

Injectable vaccines available today typically do not induce mucosal immune responses, and subunit vaccines do not typically induce strong killer T cell immune responses, which are required to produce an effective level of immunization against several difficult pathogens. Administering vaccines through non-mucosal routes often leads to poor protection against mucosal pathogens primarily because such vaccines do not generate memory lymphocytes that migrate to mucosal surfaces. Although mucosal vaccination induces mucosa homing memory lymphocytes, we believe no complete mucosal recombinant oral vaccines are commercially available. Live attenuated vaccines can pose safety risks, whereas killed pathogens or molecular antigens are usually weak immunogens when applied to intact mucosa. Moreover, the immune mechanisms of protection against many mucosal infections are poorly understood.

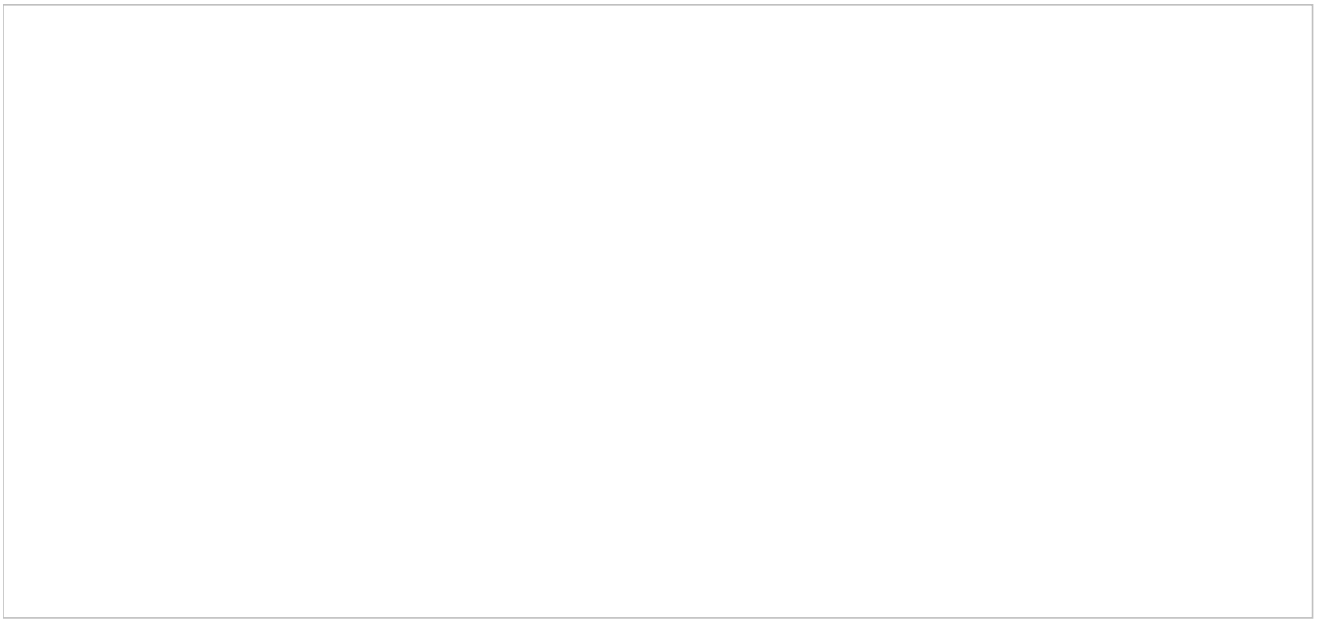
One of the key benefits of our technology is delivery to the gastrointestinal tract, enabling the vaccine to directly enter the mucosal surface of the intestine and activate the immune system of the gut. Mucosal vaccine delivery is believed to enhance protection against mucosal pathogens by generating immunity at the very surface where such pathogens invade. Our tablet vaccine candidates target the mucosal immune cells with a vector-based approach and are designed to create a more potent cytotoxic T cell response and mucosal antibody response, which may provide more effective immunity for certain diseases. Besides robust mucosal and systemic antibody responses, we observed potent and poly-functional T cell responses in our human clinical trials, demonstrating that our tablet vaccine candidates efficiently activate both B and T cells.

***Oral Non-Replicating Ad5 Vector is Designed to Circumvent Anti-Vector Issues***

Injected Ad5 vectored vaccines generate strong anti-Ad5 responses, with up to a 100-fold increase in the anti-Ad5 neutralizing antibody titers. In contrast, our oral Ad5 vectored vaccine is designed to circumvent the complications related to anti-Ad5 immunity, allowing the platform to be used for multiple vaccines and repeat annual and booster vaccinations.

Anti-vector responses have been studied in our H1 influenza Phase 1 and Phase 2 studies, as well as in the two norovirus Phase 1 studies. In the first H1 influenza oral tablet vaccine study in 12 subjects, there were no significant rises in the neutralizing antibody titers to Ad5 following immunization. A challenge study was recently performed using the same H1 flu oral tablet vaccine in more than 60 subjects. This study found a 2.2 geometric fold rise in neutralizing antibody titers to Ad5, compared to a rise of 1.1-fold in the placebo group. Finally, the rise in vaccine anti-vector immune responses were monitored in the two Phase 1 norovirus vaccine studies, study #101 and study #102. There were no significant increases in the neutralizing anti-Ad5 antibody titers following either one or two doses of vaccine, even at the high dose (see figure below).

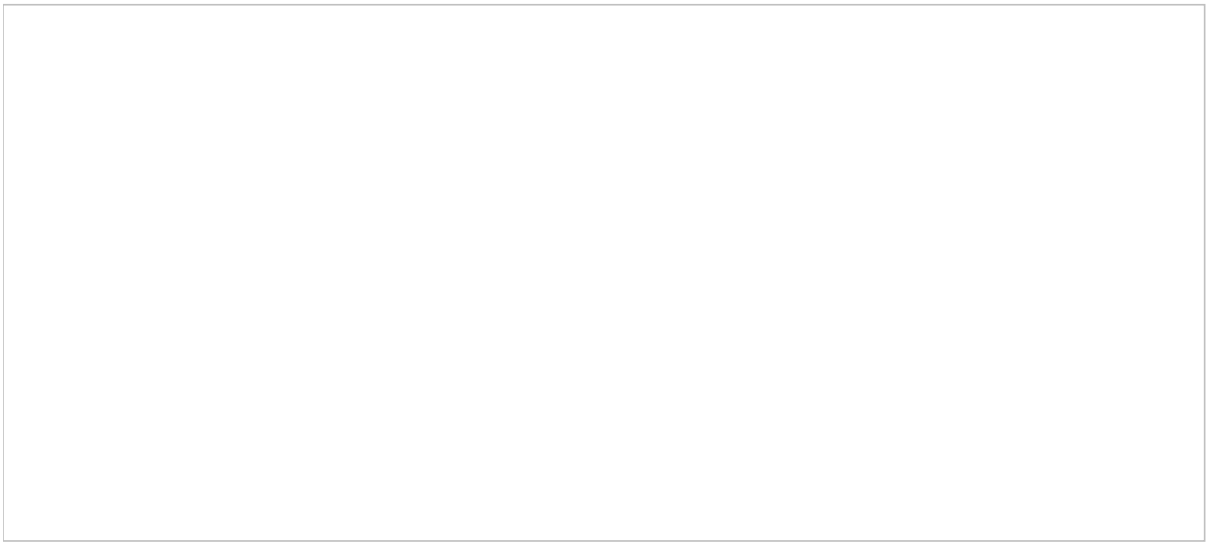
**Fig. 4.** Anti-vector titers pre- and post-immunization.



*Caption. In the single dose 101 study, anti-vector titers were measured 28 days after the only dose. In the two-dose 102 study, these were measured 28 days after the second dose. No significant increase in Ad5 titers were observed in any group in the two studies.*

In addition, in all studies to date, immune responses to the antigen of choice appeared to be independent from the recipient's pre-existing anti-Ad5 immune status. In studies with our Ad5 vectored H1 influenza oral tablet vaccine, the pre-existing antibody titers to Ad5 had no effect on the ability of the vaccine to induce a neutralizing antibody response (by hemagglutinin inhibition or microneutralization assay) to influenza. In the two recently completed Phase 1 studies with our Ad5 vectored norovirus GI.1 oral tablet vaccine, the ability of the vaccine to generate a rise in antibody titers to norovirus or specifically blocking titers to norovirus virus-like particles, or VLP (BT50 assay), was not reduced in subjects with pre-existing anti-Ad5 antibody titers. These results are shown below. In conclusion, performance of our Ad5 vectored vaccine delivered orally does not appear to be adversely affected by the pre-existing serum antibody status of the recipient.

**Fig. 5.** Anti-vector immunity had no effect on the ability of the norovirus vaccine to induce BT50 titers.



*Caption. Subjects in the high dose groups were divided based on the preexisting anti-Ad5 titers on day 0. Those with titers ≥ 100 were considered Ad5 positive, those <100 were considered Ad5 negative. The fold increase in BT50 titers for each subject were plotted. Average increase in the BT50 titers for the Ad5 positive group were not lower than the BT50 Ad5 negative group.*

**Our Norovirus Program**

***Market Overview***

Norovirus is the leading cause of vomiting and diarrhea from acute gastroenteritis among people of all ages in the United States. Each year, on average, norovirus causes 19 to 21 million cases of acute gastroenteritis, and contributes to 56,000 to 71,000 hospitalizations and 570 to 800 deaths, mostly among young children and older adults. Typical symptoms include dehydration, which is the most common complication, vomiting, diarrhea with abdominal cramps, and nausea. In a study conducted by the CDC and Pittsburg School of Medicine in 2012, the total economic burden of norovirus in the United States has been estimated at $5.5 billion. In the U.S., we believe a norovirus vaccine would be beneficial for high risk groups such as children 0-5 years old, older adults and the elderly, as well as for workers in the food and travel industries, for healthcare, childcare and elderly care workers, first responders, the military, and finally leisure travelers as well as business travelers. In a study published by Johns Hopkins University and the CDC in 2016, the total global economic burden of norovirus was estimated at $60 billion, $34 billion of which occurred in high income countries including the United States, Europe and Japan. There are currently no approved vaccines or therapies to prevent or treat norovirus infection.

***Our Norovirus Vaccine Candidate***

We plan to develop a VP1-based bivalent oral tablet vaccine that protects against norovirus GI and norovirus GII, the two major norovirus genogroups affecting humans, by targeting the norovirus GI.1 Norwalk strain and the norovirus GII.4 Sydney strain. We believe that our tablet vaccine would have important advantages over the injectable vaccine in development by Takeda. Because norovirus is an enteric pathogen that infects epithelial cells of the small intestine, we believe that a vaccine that produces antibodies in the intestine against norovirus locally in the intestine, such as our tablet vaccine candidate which is delivered directly to the gut, may be optimal at protecting against infection. The main isotype of antibodies found at the intestinal mucosal surface is IgA, whereas the main isotype of protective antibodies found in serum is IgG. We have demonstrated in our seasonal influenza clinical trials and in preclinical norovirus studies that our vaccine candidates can generate mucosal IgA antibodies to the antigen encoded in our vaccine.

***Preclinical Results***

We have conducted multiple preclinical studies of our norovirus vaccine candidate in mice and ferrets. Overall, as compared with injectable VP1 protein vaccine, our norovirus vaccine candidate generated comparable levels of serum antibody and superior levels of mucosal antibody to the VP1 injectable protein vaccine.

***Clinical Trials***

We have completed two Phase 1 studies with our monovalent norovirus GI.1 oral tablet vaccine, one of the two strains that will be included in the bivalent vaccine. In both Phase 1 studies, the primary endpoint was safety and the secondary endpoint was immunogenicity.

**Study 101. Placebo Controlled Study**

In the Phase 1 study designed to evaluate the norovirus vaccine (VXA-GI.1-NN), 66 healthy adults were randomized in three groups, with 23 subjects receiving a single low dose of 1 x $10^{10}$ infectious units, or IU, 23 subjects receiving a single high dose of 1 x $10^{11}$ IU, and 20 subjects randomized to the placebo control.

**Safety Results. 101 Study**

*Solicited Events.* In the first 7 days following study drug administration, 35 study subjects had at least one solicited adverse event (AE) reported with 25/46 (54%) subjects in the VXA-GI.1-NN vaccine groups and 10/20 (50%) of subjects in the placebo group (See table below). All of the solicited AEs reported (n=46) were grade 1 or 2 in severity with the majority being mild events (44 grade 1 and 2 grade 2 events). The percentage of subjects with any solicited symptoms was similar among treatments (See table below). Diarrhea and headache were the most common solicited symptoms following VXA-GI.1-NN administration, both reported by 15 (33%) subjects in the treated groups. Headache and nausea were reported evenly across treatments, including placebo. The only solicited symptom demonstrating a statistically significant difference from placebo was diarrhea ($p = 0.0275$), reported by 11 subjects in the high dose group. Nine of the 11 subjects reported mild severity diarrhea, while 2 subjects reported moderate severity episodes following the high dose vaccine. Onset of diarrhea (verbatim term "loose stools") ranged from day 1 to day 6 following vaccine administration, and most episodes resolved within 1 day. At no point did any of the loose stools impact normal activity such as work or school, and none required treatment with anti-diarrheal medications or rehydration therapy. In summary, the vaccine appeared well-tolerated without causing any dose limiting toxicities.

**Table 1.** Norovirus Study 101 Solicited Systems – Number and Percent of Subjects Reporting Treatment Emergent Adverse Events.

| Adverse Events* | Placebo N=20 | Low Dose N=23 | High Dose N=23 |
|---|---|---|---|
| **Number of Subjects with Any Symptoms** | 10 (50%) | 11 (48%) | 14 (61%) |
| **Gastrointestinal disorders** | | | |
| Abdominal pain | 2 (10%) | 5 (22%) | 0 (0%) |
| Diarrhea | 3 (15%) | 4 (17%) | 11 (48%) |
| Nausea | 4 (20%) | 4 (17%) | 3 (13%) |
| **General disorders and administration site conditions** | | | |
| Malaise | 2 (10%) | 1 (4%) | 3 (13%) |
| **Nervous system disorders** | | | |
| Headache | 8 (40%) | 8 (35%) | 7 (30%) |

*Solicited symptoms were collected from subjects for 7 days following immunization.*

*Unsolicited Events.* A total of 83 unsolicited Treatment Emergent Adverse Events, or TEAEs, were reported by 33 of the 66 subjects within the first 28 days post dosing, with slightly more placebo subjects 12/20 (60%) reporting AEs than low dose 11/23 (48%) or high dose vaccinated subjects 10/23 (44%). Headache was the most common AE reported in all treatments. Most TEAEs were mild or moderate in severity. The PI considered 28 TEAEs possibly related, 42 unlikely related, and 13 not related.

**Study 102. Dose and Schedule Optimization**

The study was designed to evaluate the norovirus vaccine (VXA-GI.1-NN) in 60 subjects given multiple doses, with some differences in schedule for the lower dose groups. The first three groups enrolled (N=15 each) used low doses of 1 x $10^{10}$ infectious units (IU). Group A received two doses of VXA-GI.1-NN on days 0 and 7, group B received three doses on days 0, 2, and 4, and group C received two doses on days 0 and 28. The fourth group, group D (N=15), evaluated two high doses of 1 x $10^{11}$ IU given on days 0 and 28. The vaccine study was an open labeled study, and enrolled more or less sequentially from group A to group D. The primary endpoint of the study was to evaluate the safety of all dosing regimens and the secondary endpoint was to compare immunogenicity between groups by BT50 titers and antibody secreting cells (ASC) counts.

**Safety Results. 102 Study**

In the first 7 days following study drug administration, there were 27 subjects reporting adverse events, distributed across the groups with the highest number of reporting adverse events in group C (11/15) and the lowest in group D (3/15). The most common adverse event reported was headache, reported in 21 subjects out of 60. Group C reported the highest number of headaches, and adverse events overall. This group was given two low dose vaccines 28 days apart. This was not observed in group D, a vaccine group given the exact same dosing schedule, but receiving two 10-fold higher doses of vaccine.

**Table 2.** Norovirus Study 102 Solicited Systems – Number and Percent of Subjects Reporting Treatment Emergent Adverse Events.

| SYSTEMIC ORGAN CLASS /Preferred Term | Group A N=15 | Group B N=15 | Group C N=15 | Group D N=15 |
|---|---|---|---|---|
| **Total Number Reporting an Adverse Event** | 5 (33.3%) | 8 (53.3%) | 11 (73.3%) | 3 (20%) |
| **GASTROINTESTINAL DISORDERS** | | | | |
| Diarrhea | 0 | 1 (7%) | 5 (33%) | 1 (7%) |
| Abdominal Pain | 1 (7%) | 0 | 3 (20%) | 1 (7%) |
| Nausea | 1 (7%) | 2 (13%) | 2 (13.3%) | 0 |
| Abdominal Pain, Upper | 0 | 1 (7%) | 0 | 0 |
| **GENERAL DISORDERS** | | | | |
| Malaise | 2 (13%) | 0 | 2 (13%) | 1(7%) |
| Feeling Hot | 0 | 1 (7%) | 0 | 0 |
| **NERVOUS SYSTEM DISORDERS** | | | | |
| Headache | 4 (27%) | 7 (47%) | 9 (60%) | 1 (7%) |

**Group A:** Low Dose - Day 0, 7 **Group B:** Low Dose - Day 0, 2, 4 **Group C:** Low Dose - Day 0, 28 **Group D:** High Dose - Day 0, 28

*Solicited symptoms were collected from subjects for 7 days following immunization.*

**Safety Summary from the Two Studies.**

106 subjects were treated with VXA-GI.1-NN in the two norovirus vaccine studies. The vaccine was well tolerated, with no severe adverse events reported in either study. The most common solicited adverse event was headache, but this was relatively similar among all the dosing groups including 40% of subjects receiving the placebo in the 101 study. In the 101 study, there was a higher incidence of diarrhea reported in the high dose group versus the other groups. However, in the high dose group in the 102 study, there was only 1 subject (6.7%) reporting diarrhea even after receiving two high doses. These results in total suggest that there were no dose dependent effects that impacted safety.

***Immunogenicity Results-Study 101***

**BT50 Titers**. The primary immunological endpoint was to measure antibody titers by an assay that assessed the ability of antibodies to block interaction of a norovirus VLP to histogroup blood antigen (HGBA). This assay is known as the BT50 (for 50% inhibition of blocking titer) assay. BT50 titers were assessed using $Le^b$ synthetic glycan as the coating antigen. Titers rose in the vaccine recipients, and at all timepoints (Figure 6). By the $Le^b$ BT50 assay, 14/23 (61%) of the subjects in the low dose group, and 18/23 (78%) in the high dose group, had at least a two-fold rise. One subject in the placebo group had a greater than two-fold rise. On Day 28, the geometric mean titer (GMT) for the low dose vaccine group was 59.0, a 2.3-fold geometric mean fold rise (GMFR) over the initial GMT of 26.2 at baseline. The GMT for the high dose vaccine group was 98.5, a 3.8-fold GMFR over the initial GMT of 25.8 at baseline. The high dose group was significantly increased over placebo on day 28 (P=0.0003). Complete results are given in the table below.

***GMT for $Le^b$ BT50 assays***

**Table 3.** Study 101, Least Squared Geometric Mean Titer (LSGMT) for $Le^b$ BT50 assay.

| HBGA | $Le^b$ | | | |
|---|---|---|---|---|
| Group | D0 LSGMT (95 CI) | D28 LSGMT (95 CI) | LSGMR | p value* |
| Low | 26.2 (16.6-41.2) | 59.0 (33.0-105.4) | 2.3 | 0.0459 |
| High | 25.8 (18.3-36.2) | 98.5 (64.4-150.7) | 3.8 | 0.0003 |
| Placebo | 24.6 (15.3-39.3) | 27.4 (17.0-44.2) | 1.1 | Reference |
| | Overall significance | | | 0.0017 |

**Significance by Mann-Whitney vs placebo; overall significance by Kruskal-Wallis Test.*

**Antibody Secreting Cell (ASC).** The ability of the vaccine to induce norovirus specific B cells in the peripheral blood was measured by ASC assay. This assay essentially counts the number of B cells that emerge after immunization and recognize norovirus in the peripheral blood. The number that circulate in the blood pre-immunization is very low, so the assay is a meaningful way to evaluate the vaccine specific effects. In the low dose group, 16/23 (70%) of subjects responded and in the high dose group, 19/23 (83%) of subjects responded on day 7 for both IgA and IgG ASCs (Figure 7). Background ASCs were generally negligible on day 0. For the high dose vaccine treated group, an average of 561 IgA ASCs and 278 IgG ASCs each per 1 x $10^6$ peripheral blood mononuclear cells, or PBMC, were found on day 7. For the low dose vaccine treated group, an average of 372 IgA ASCs and 107 IgG ASCs were found on day 7. The placebo group had no responders with an average of 3.3 spots for IgA ASCs and 2.2 spots for IgG ASCs per 1 x $10^6$ PBMC on day 7. The treated groups were significantly different than placebo in terms of the ability to elicit an IgG or an IgA ASC response at day 7 ($P<0.0001$, Mann-Whitney). There was no statistical difference in the number of spots for IgA and IgG ASCs between the high and low dose groups ($P=0.21$ for IgA, $P=0.28$ for IgG).

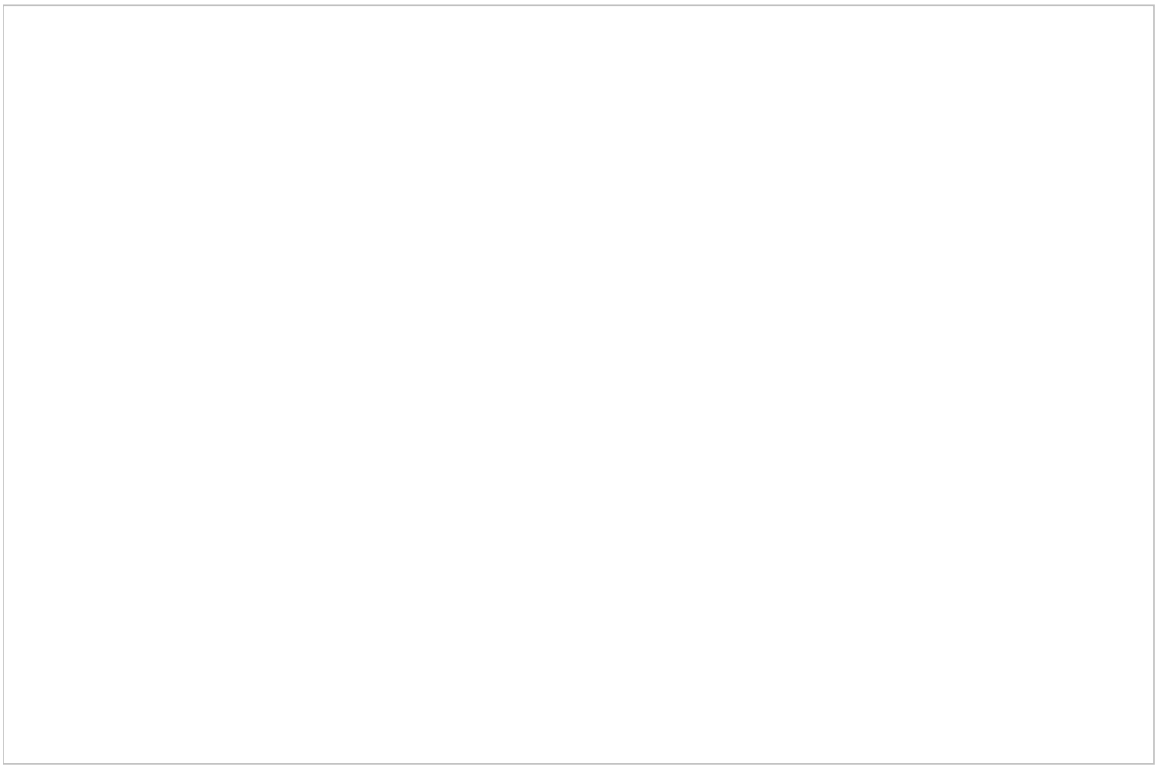
**Enzyme-linked immunosorbent assay (ELISA) IgA and IgG.** Serum antibody responses were measured by IgG and IgA ELISA, and the changes in titers at EC50 between days 0 and 28 were calculated for each subject. Most subjects had an increase in antibody titers post immunization. The average change in EC50 for the low dose group was 16 and 7.1-fold in IgA and IgG respectively. Similarly, the average change in the EC50 for the high dose group were 9 and 5.4-fold for IgA and IgG respectively. The change in EC50 are plotted for each subject, separated by group (Figure 8).

**Memory Cells.** Memory cells are long-lived cells that are important for the rapid induction of immunity following infection. A goal of most vaccines is to safely induce immunological memory to protect people from actual infection. Antigen specific memory B cells were investigated after culturing PMBCs with polyclonal stimulators. VP1 specific IgG memory B cells were higher than IgA memory B cells in the day 0 samples (Figure 9). Post immunization, the response at day 7 was higher for IgA memory B cells, with a geometric mean fold rise, or GMFR, of 15.3 for IgA versus 6.5 for IgG between day 0 and 7, before declining again at day 28. In the low dose group, the GMFR was 7.4 for IgA and 3.7 for IgG was observed between days 0 and 7. This decline from day 7 to day 28 may have resulted from homing of circulating B cells from the peripheral blood to the intestinal lymphoid tissues via expression of high levels of the mucosal homing receptor, $\alpha4\beta7$. In the high dose group at day 7, 20/23 (87%) IgA and 19/23 (83%) for IgG showed $\geq$ 2-fold increase over day 0. In the low dose group at day 7, 18/23 (78%) for IgA and 13/23 (57%) for IgG showed $\geq$2-fold increase over day 0.

**Fecal and Saliva IgA.** Norovirus VP1 specific mucosal IgA was explored directly by looking at fecal and saliva samples. Because the quantity of IgA is highly variable within these samples, total IgA was also measured and the ratio between VP1- specific IgA/total IgA for each sample was examined. Samples with IgA levels below the detection limit were excluded from analysis. The increase in the ratio of specific IgA to total IgA was measured between baseline and day 28 (and baseline and day 180 for fecal IgA). In the high dose group, 9/19 (47%) fecal samples were responders with a four-fold rise or greater IgA response at day 28, and 9/21 (43%) at day 180 (Figure 10). The average fold increases in specific IgA/total IgA ratio were 17.2 and 9.7. These results are significantly higher than the placebo group where 2/18 (11%) and 0/16 (0%) were found to have 4-fold or better increases on days 28 and 180 ($P=0.029$ and $P=0.0049$ respectively), with average increases of 1.8 and 1.0 (Figure 10). The low dose group had a similar response as the high dose, with 7/20 (35%) and 5/16 (31%) with 4-fold or greater increases on days 28, and 180 respectively. The number of responders trended higher than placebo on day 28, but the difference was statistically significant on day 180 ($P=0.13$ and 0.043). The low dose group had a 36.2-fold increase on day 28, and a 5.6-fold increase on day 180 (Figure 10). Fewer subjects had detectable increases in the specific IgA to total IgA ratios in saliva samples of treated subjects at day 28 (Figure 11). The average increase in the specific IgA/total IgA ratio was 2.0 for the low dose, 2.9 for the high dose group, and 1.2 for the placebo group. The high dose and low dose groups had each had 4 subjects with a 4-fold rise in the specific response, versus none for the placebo group. These results demonstrate that the vaccine can induce antibody responses that are measured in the mucosa, particularly in the intestinal mucosa, which is the site of norovirus infection.

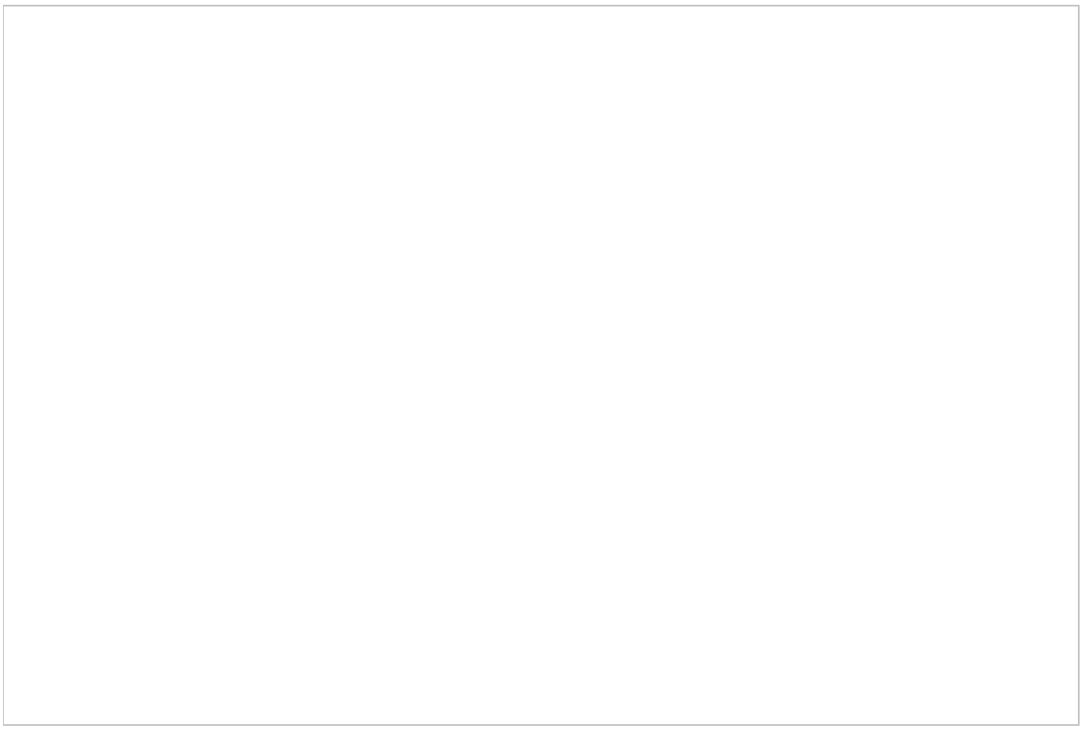
Table of Contents

**Fig. 6.** Geometric Mean Titers vs Time.



*Caption. Geomean Serum BT50 Titers over time for Le$^{b}$.*

**Fig. 7.** ASC Titers on Day 7 post immunization.



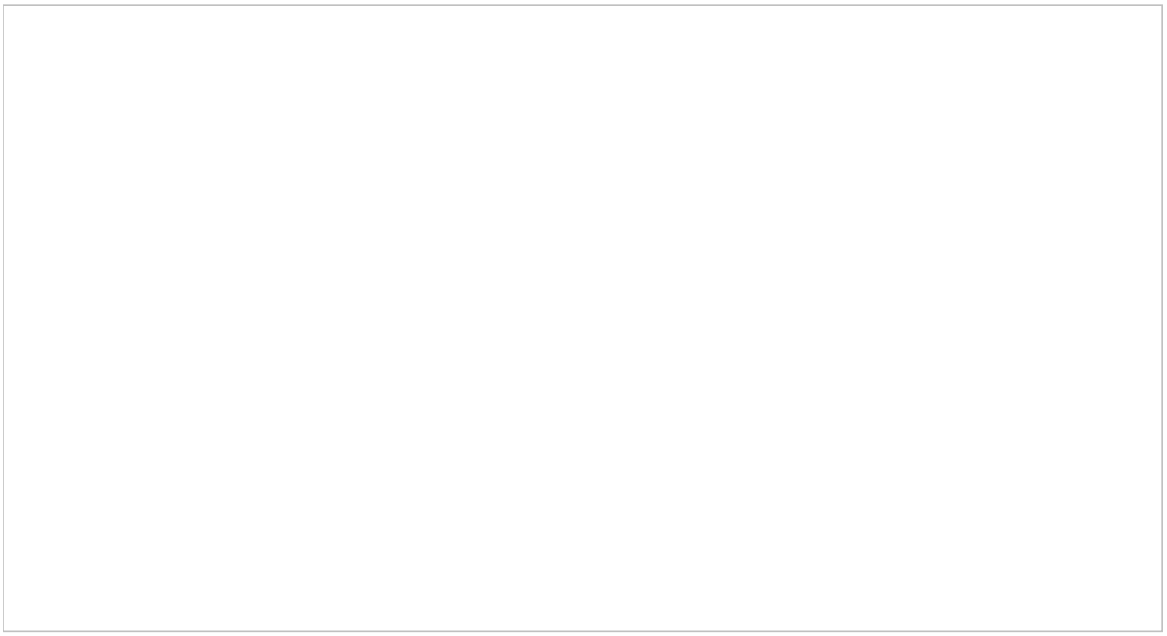
*Caption: ASC counts on day 7 for both IgG and IgA responses to norovirus VLP. This assay measures antigen specific B cells in the peripheral blood that occur post vaccination.*

**Fig. 8.** ELISA antibody changes post immunization.

*Caption. Change in IgA or IgG ELISA titers post immunization between days 0 and 28 for all subjects divided by treatment group. Each symbol represents an individual subject. The long horizontal line represents the mean, with the smaller lines the 95% confidence interval.*

Table of Contents

**Fig. 9.** Memory Cell Responses pre- and post-immunization.

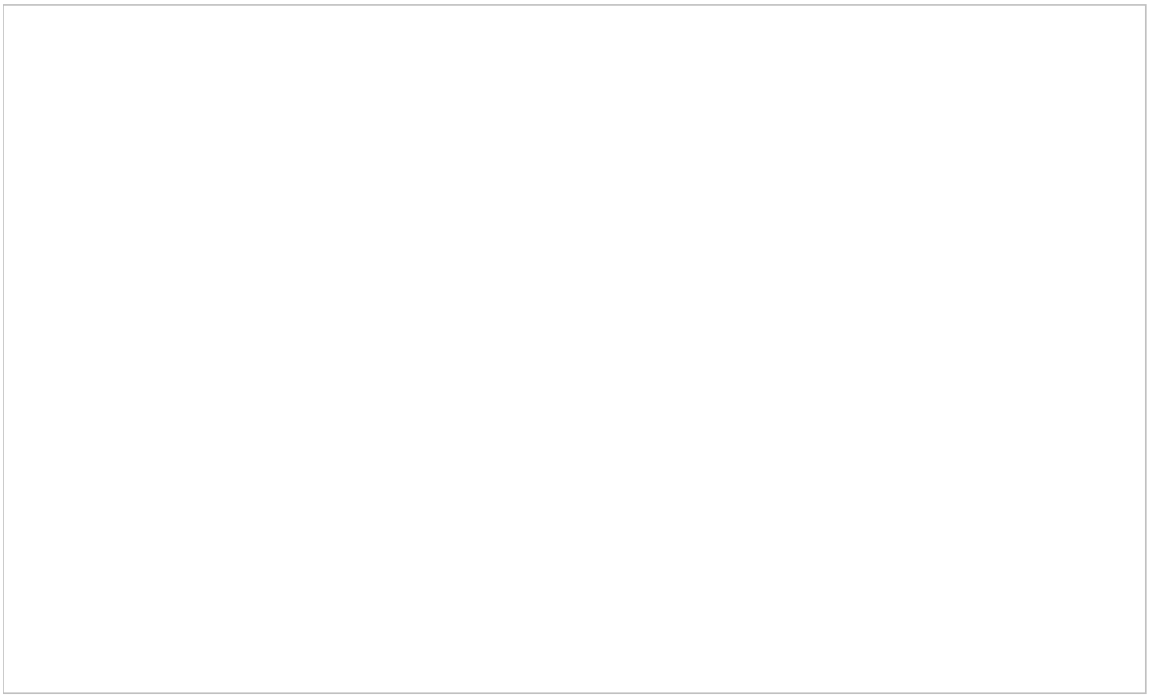


*Caption: Norovirus VP1 specific memory B cell counts were plotted for each time point. Each symbol represents an individual subject. The long horizontal line represents the geometric mean.*

**Fig. 10.** Fold Induction in Norovirus Specific Fecal IgA Responses Post Immunization.

*Caption. Fecal responses to the vaccine, with fold increase in specific IgA/total IgA for each subject (divided by group and each timepoint) plotted. Average increase is the black bar.*

**Fig. 11.** Fold Rise in Norovirus Specific Responses in Saliva.



*Caption. Saliva IgA responses were measured. The plot shows fold rise of specific IgA/ total IgA post immunization. Responses were compared between days 0 and 28.*

***Immunological Results - 102 Study***

**BT50 Titers.** The objective of the study was to compare schedules and dosing for the ability to elicit immune responses, particularly by evaluating BT50 titers. BT50 titers were assessed at multiple times points, given that multiple doses were given. In the high dose group, 12 of 15 subjects had a 2-fold or greater increase in BT50 titers after the first dose and 14 of 15 subjects (92%) had a 2-fold or greater increase in BT50 titers after 2 doses. The GMT titer rose from 21.3 on day to 85.1 on day 28 for a 3.8 GMFR. The GMT at day 56 were measured to be 75.8, a GMFR of 3.6 over the baseline values. Other groups given lower doses of vaccine had lower response rates. Groups A and C had higher increases in the titers compared to Group B, although this is not statistically significant. An ANCOVA model was used to determine the statistical significance of the increases in GMFR. Least-squares, or LS, geometric mean titers, or LSGMTs, and LS geometric mean fold rises (LSGMFRs) were calculated by exponentiating the LSMs from the ANCOVA model, which included log-transformed post baseline titer or log-transformed change from baseline titer as a dependent variable, cohort as a factor, and baseline log-titer as a covariate. The significance in the different groups to increase the GMFR (test is LSGMFR=0), was found to be P=0.0008, 0.1224, 0.0004, and <0.0001 for groups A through D respectively at day 56. This means all groups had statistically significant increases in the GMT with the exception of group B, which had a more modest increase in the titers.

***102 Study. BT50 Titers, Le$^b$***

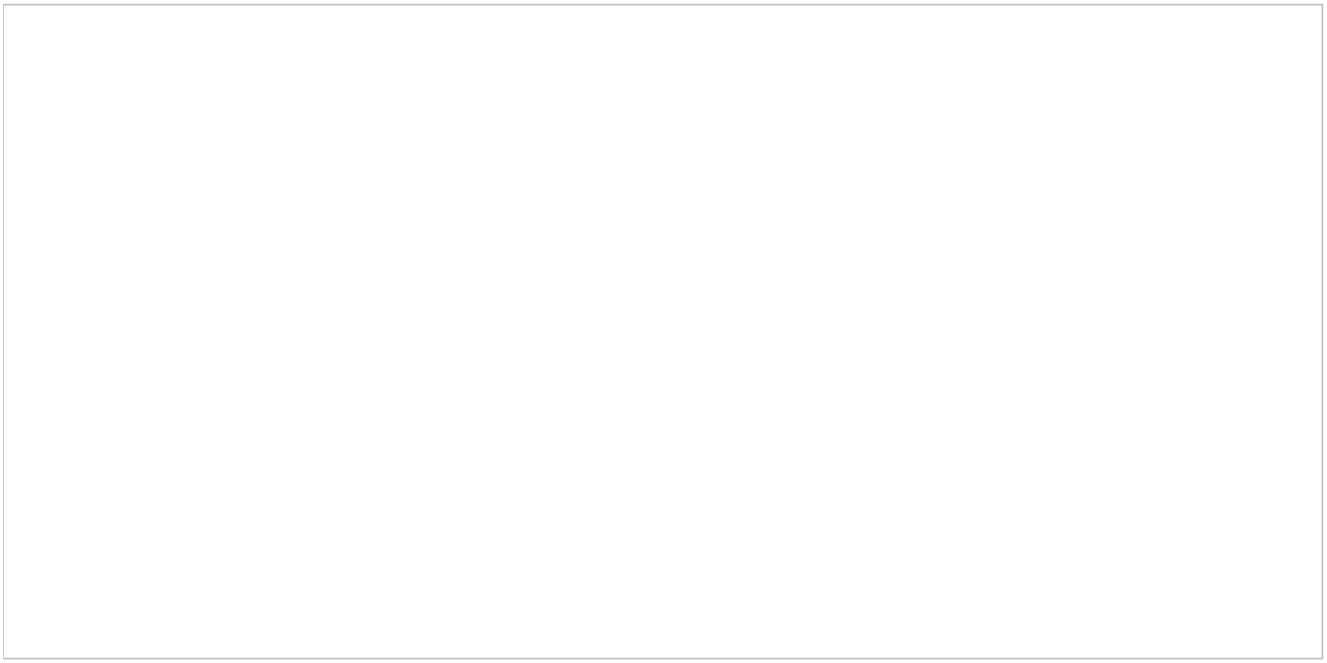
**Table 4.** Study 102, Geometric Mean Titer(GMT) for Le$^b$ BT50 assay roger.

| Group | Description | DO GMT | D28 (or D36) | GMFR | GMT D56 | GMFR D56 |
|---|---|---|---|---|---|---|
| **A** | **Low, 2X, 7 days apart** | 32.2 | 64.5 | 2.0 | 66.0 | 2.0 |
| **B** | **Low, 3X, 2 days apart** | 31.5 | 51.2 | 1.6 | 42.5 | 1.4 |
| **C** | **Low, 2X, 28 days apart** | 29.4 | 66.0 | 2.2 | 64.5 | 2.2 |
| **D** | **High, 2X, 28 days apart** | 21.3 | 85.1 | 3.8 | 75.8 | 3.6 |

**ASCs.** Additional immunological analysis was performed by comparing the ASC responders between groups. The high dose group had 14 out of 15 subjects respond to the vaccine, with an average IgA ASC count of 698 per 1X10 $^6$ cells. Following a second dose, the subject that didn't respond the first time had a significant increase in ASC counts so all 15 subjects (100%) were able to elicit an ASC response following two doses. As typical, subjects that had a high number of ASC counts after the first immunization had a low response after the 2$^{nd}$ dose. The low dose groups were compared by examining the overall response rate, since the dosing and the analysis were performed at different intermediate timepoints. Group A had the highest overall response rate where 12/14 subjects (86%) were able to induce meaningful ASC responses after 1 or 2 doses. Slightly lower responders were observed in group B, where only a few subjects had a response after the first dose, but more subjects responded after additional vaccine doses. Group C had the most variable responses of any group. The average number of spots was 839 per 1X10$^6$ cells after the first dose, but this was the result of several subjects having extremely high numbers of spots (3 subjects had greater than 1500 per 1X10$^6$), mixed with many subjects that didn't respond at all.

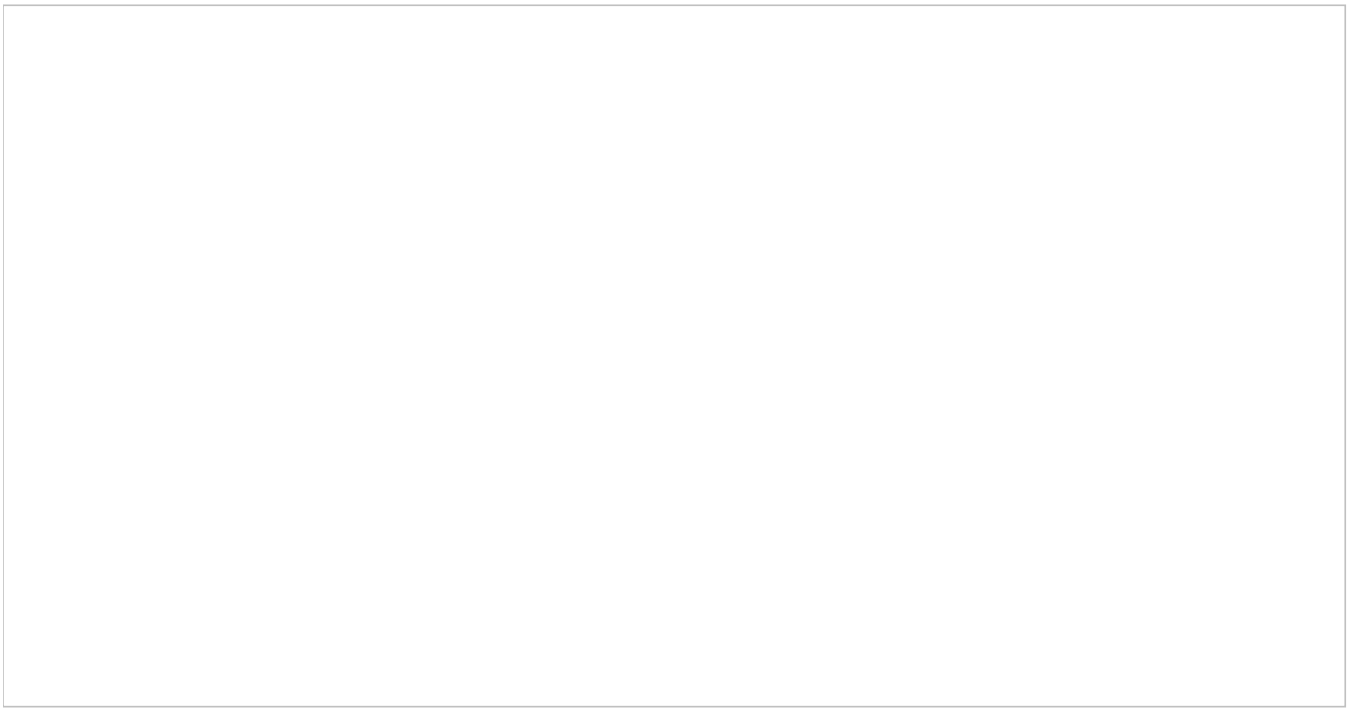
By Fisher's Exact test, the high dose group induced a higher number of responders than group C p=0.02), but only trended higher than groups A and B (0.22, 0.07). Similar results were observed for the IgG ASC responses, with slightly lower values on average.

**Fig. 12.** IgA ASC Counts for the 102 study.



*Caption. The different groups were assessed for IgA ASC counts at each time point taken for each group. Because there were different dosing regiments for each group, there were different timepoints assessed. Response rates at each timepoint are indicated by a fraction and a percentage below each timepoint. The overall response rate (the total number of subjects that responded at any time point) is given near the top of each group. For example, in the last group, 15/15 (100%) subjects responded at either D7 or D35.*

**Fig. 13.** IgG ASC Counts for the 102 Study.



*Caption. The different groups were assessed IgG ASC counts at each time point taken for each group. Because there were different dosing regiments for each group, there were different timepoints assessed. Response rates at each timepoint are indicated by a fraction and a percentage below each timepoint. The overall response rate (the total number of subjects that responded at any time point) is given near the top of each group. For example, in the last group, 15/15 (100%) subjects responded at either D7 or D35.*

**Norovirus Oral Tablet Vaccine Clinical Development Pathway**

***Phase 1 Bivalent Norovirus Trial***. The bivalent Phase 1 trial is designed to assess the safety and immunogenicity of the two individual GI.1 and GII.4 norovirus vaccines, and to evaluate potential interference between the two vaccines. The trial is scheduled to begin during the first half of 2019.

***Phase 2 Norovirus GI.1 strain Challenge Study.*** We plan to commence a challenge study with our monovalent GI.1 norovirus vaccine candidate in the first half of 2019.

***Phase 2 Efficacy and Safety Trial***. After successfully completing the trials described above, a Phase 2 trial would be conducted. This trial will be designed to assess the safety, immunogenicity and possibly the efficacy of the bivalent vaccine in an expanded population of adults ranging in age from 18 to 49 years.

***Path to Approval***. After completing the Phase 2 trial, we expect to request an End-of-Phase 2 meeting with the FDA to discuss the design of a Phase 3 trial that would support licensure.

***Additional Age Groups***

- ***Older Adults, Elderly Population***. Following successful completion of the bivalent Phase 1 trial in healthy adults age 18 – 49, we plan to conduct sequential Phase 1 and Phase 2 clinical trials in healthy adults age 50 – 64 years and age 65 and older, designed to support licensure of our tablet vaccine candidate for these age groups. Following these studies, we expect to engage in discussions with the FDA to determine the requirements for Phase 3 and licensure.
- ***Pediatric Population***. Our current tablet vaccine candidates are designed for delivery to the gut in solid dosage form using an enteric-coated tablet which we believe is the optimal vaccine delivery system for the adult population and children 8 years and older. For children 6 months to 8 years in age, we plan to develop proprietary liquid formulations that can deliver the vectored vaccine intact to the gut. Development of our norovirus vaccine product candidate in the pediatric population will proceed stepwise through progressively younger age segments (i.e. 9-17 years, 5-8 years, 2-4 years, 6 weeks-2 years).

**Our Seasonal Influenza Program**

***Market Overview***

Influenza is one of the most common global infectious diseases, causing mild to life-threatening illness with symptoms such as sore throat, nasal discharge, fever, and even death. It is estimated that at least 350 million cases of seasonal influenza occur annually worldwide, of which 3 million to 5 million cases are considered severe, causing 290,000 to 650,000 deaths per year globally. Very young children and the elderly are at greatest risk from death. In the United States, between 5% and 20% of the population contracts influenza, 226,000 people are hospitalized with complications of influenza, and between 3,000 and 49,000 people die from influenza and its complications each year, with up to 90% of influenza-related deaths occurring in adults older than 65.

According to a CDC commissioned-report based on 2003 population figures, in the United States, seasonal influenza costs an average of over 600,000 life-years lost, 3.1 million hospitalized days, and 31.4 million outpatient visits annually. The total economic burden of seasonal influenza has been estimated to be $87.1 billion, including medical costs which average $10.4 billion annually, while lost earnings due to illness and loss of life amount to $16.3 billion annually.

The CDC generally recommends that individuals 6 months and older be vaccinated annually against influenza. In the U.S., this means an influenza vaccination is recommended for more than 300 million people. During the 2017/2018 influenza season, approximately 137 million doses of the influenza vaccine were delivered in the United States. Differentiated flu vaccines in the U.S. market continue to demonstrate the ability to ask for premium prices based on the additional value they provide to public health. According to a 2017 Datamonitor Healthcare report the seasonal influenza vaccines market within the United States and five major European Union markets (France, Germany, Italy, Spain, and the UK) will increase from $2.7 billion in the 2016/17 season to $3.4 billion in the 2025/26 season. We believe, worldwide, the primary drivers of market growth include increasing awareness, increasing vaccination coverage in emerging countries, rising government support for immunization against seasonal influenza, pricing increases due to product differentiation and increased focus on the production and advancement of vaccination treatments.

***Limitations of Current Seasonal Influenza Vaccines***

Despite the number of cases of influenza diagnosed in the United States, according to the CDC, in the 2017/2018 seasonal influenza season, only approximately 42% of the total U.S. population was vaccinated against influenza, with particularly low vaccination rates among adults between ages 18 and 49. According to the CDC, less than 27% of adults between ages 18 and 49 were vaccinated during the 2017/2018 influenza season. We believe the low vaccination rates among this population are largely attributed to the following limitations of injectable vaccine administration:

***Limitations for Providers***

- longer manufacturing, shipping and handling time for suppliers;
- cold storage requirement throughout the logistics chain;
- the need for healthcare professional oversight during and after the vaccination procedure;
- potential for needle injuries; and
- medical waste.

***Limitations for Users***

- inconvenience and time commitment required to obtain vaccine at a clinic or pharmacy;
- fear of needles;
- pain at injection site; and
- potential for allergic reactions to the egg component of the vaccine.

***Our Seasonal Influenza Vaccine Candidate***

We are developing a tablet vaccine candidate for the immunization of healthy adults against seasonal influenza. Our seasonal influenza vaccine candidate is being designed to cover the four-strain, or quadrivalent, seasonal influenza vaccine consisting of two circulating influenza A lineage viruses as well as two circulating influenza B lineage viruses, matching the seasonally updated recommendations by the FDA. We envision formulating our tablet vaccine candidate as one tablet per strain, or four tablets in total for the quadrivalent vaccine. We believe this modularity will allow for enhanced flexibility. For instance, in the event of a late season strain change, the tablet containing the obsolete strain could be easily replaced without having to discard the three correctly matched vaccine tablets. Further, given stability of the tablets, excess tablets from one season could be stored and utilized in the next season, while fully formulated quadrivalent vaccines would have to be discarded at the end of each season as is the case with currently marketed influenza vaccines. Alternatively, we have the option to formulate all four strains into a single tablet. This format would be the simplest to administer, but would take away some of the flexibility advantages that separate tablets would afford. We will assess the final formulation of our tablet vaccine candidates after conducting market studies to evaluate market acceptance closer to commercialization.

We believe our tablet vaccine candidates have the potential to address many of the limitations of current injectable, egg-based seasonal influenza vaccines. First, our tablet vaccine candidates are designed to create broad and durable immune responses, which may provide more effective immunity and protect against additional strain variants. Second, by providing a more convenient method of administration to enhance patient acceptance and simplify distribution and administration. Finally, by using recombinant methods, we believe our tablet vaccine candidates may be manufactured more rapidly than vaccines manufactured using egg-based methods, eliminate the risk of allergic reactions to egg protein, and alleviate issues caused by egg-adaptation of a mammalian virus.

***Seasonal Influenza Clinical Trials***

To date, we have completed two Phase 1 trials and have conducted the active portion of a Phase 2 challenge trial of our H1N1 influenza vaccine candidate. We have also completed a Phase 1 trial of an influenza B vaccine candidate.

***Phase 1 Trial, VXA02-001, H1N1 Influenza Vaccine Candidate, $10^9$ and $10^{10}$ IU Doses***

The first Phase 1 H1N1 trial was conducted at doses of 1 x $10^9$ and 1 x $10^{10}$ IU. Two doses were given one month apart. The tablet vaccine candidate generated a favorable safety and tolerability profile. The trial also demonstrated robust T cell responses and modest hemagglutination inhibition assay, or HAI, responses, each dependent on the dosage level.

***Phase 1 Trial VXA02-003, H1N1 Influenza Vaccine Candidate, $10^{11}$ IU Dose***

The second H1N1 trial was a tablet vaccine trial at a dose of 1 x $10^{11}$ IU, delivered in a single administration. We observed a favorable safety and tolerability profile at this dose level. An HAI seroconversion rate of 75% was measured in the vaccine group, compared to 0% in the placebo group. 92% of subjects had a four-fold increase in Micro Neutralization, or MN, titer after the single administration of tablets. Both the HAI seroconversion rate and the MN responses were substantially higher than the respective rates that we observed at lower doses in Trial VXA02-001. The side effects of the vaccine or placebo in the first seven days following administration were mild with no serious adverse effects. In the first seven days following administration, there were eight total solicited adverse events, or AEs, reported in the vaccine and placebo groups (four in each group). All of these AEs were grade 1 in severity. The most frequent AE was headache (two in placebo, and one in the vaccine group). There were no serious adverse events and no new onsets of chronic illnesses related to the adjuvant recorded during the entire one year follow up period of the study.

The table below summarizes the trial design and results (serum antibody responses) of our two placebo-controlled Phase 1 H1N1 clinical trials.

**Table 5.** Overview: H1 Influenza Phase 1 Placebo-Controlled Studies.

| TRIAL NO./ # SUBJECTS | TRIAL DESIGN | STUDY GROUPS DOSE/SCHEDULE | KEY IMMUNOGENICITY FINDINGS |
|---|---|---|---|
| **Phase 1 Trial VXA02-001 N = 36** | Dose-escalation, placebo-controlled, double-blind with enteric-coated capsules | $10^9$, $10^{10}$ IU of VXA-A1.1 (H1) vaccine or placebo on Day 0 and Day 28, administered in tablet form | $10^9$ dose level:<br>• No HAI seroconversion<br><br>$10^{10}$ dose level:<br>• 27% HAI seroconversion<br>• 64% MN (4X rise) |
| **Phase 1 Trial VXA02-003 N = 24** | Placebo-controlled, double-blind, with enteric-coated tablets | $10^{11}$ IU VXA-A1.1 (H1) vaccine or placebo on Day 0, single administration in table form | • 75% HAI seroconversion<br>• 92% MN (4X rise) |

***Phase 1 Trial. Influenza B***

In 2015 and 2016, we conducted a randomized, double-blind, placebo-controlled Phase 1 trial to test the safety and immunogenicity of an influenza B tablet vaccine. A total of 54 healthy adults age 18-49 were enrolled, with 38 receiving the vaccine and 16 receiving placebo. To participate in this trial, subjects were required to have an initial HAI measure of no greater than 1:20. The active phase of the trial was through day 28, with the follow-up phase for monitoring safety to continue for one year. All subjects who received the vaccine received a single dose of either 1 x $10^{10}$ IU or 1 x $10^{11}$ IU on Day 0.

***Safety***. The side effects of the vaccine or placebo in the first seven days following administration were generally mild with no serious adverse events. There were no notable differences between the active dose groups and placebo in safety and tolerability.

***HAI***. In the placebo group, HAI GMT remained essentially unchanged (1:33) at day 28 post dosing. The GMFR of HAI titers both active treated groups at day 28 post dosing was about 2-fold, and independent of dose. For the vaccinated groups receiving either $1\times10^{10}$ IU or $1\times10^{11}$ IU, seroconversion was observed in 5/19 subjects (26.3%) and 3/19 subjects (15.8%), respectively. There were no seroconversions in the placebo group.

***Antibody Secreting Cells (ASCs).*** In order to measure total antibody responses to HA, the numbers of circulating B cells that recognize influenza HA in peripheral blood were measured by ASC assay on days 0 and 7 after immunization. Results show that ASCs could be reliably measured on day 7 in the vaccine-treated groups. Background ASCs were generally negligible on day 0. By IgG ASC, 68% of $1\times10^{10}$ IU dose subjects responded, and 84% of subjects in the $1\times10^{11}$ IU dose group responded. For the $1\times10^{11}$ IU dose vaccine treated group, an average of 21 IgA ASCs (95% CI: 7 – 35) and 73 IgG ASCs (95% CI: 35 – 111) each per $1\times10^{6}$ peripheral blood mononuclear cell (PBMC) were found at day 7. For the $1\times10^{10}$ IU dose vaccine treated group, an average of 16 IgA ASCs (95% CI: 2 – 29) and 44 IgG ASCs (95% CI: 21 – 66) were found at day 7. The placebo group had no responders, and negligible average number of spots (1 or less) on Day 7 (95% CI: -0.6 – -2).

***H1N1 Influenza Phase 2 Challenge Study Funded by BARDA***

In 2015, we were awarded a $13.9 million contract by BARDA, part of the U.S. Department of Health and Human Services. This two-year contract was awarded under a Broad Agency Announcement issued to support the advanced development of more effective influenza vaccines to improve seasonal and pandemic influenza preparedness. The contract primarily funded a Phase 2 challenge study in human volunteers, designed to evaluate whether our H1N1 tablet vaccine candidate offers broader and more durable protection than currently marketed injectable vaccines. The contract with BARDA was subsequently increased to $15.7 million and the term was extended until September 2018.

In this Phase 2 study, volunteers were randomized into three groups. One group received our oral H1N1 influenza tablet vaccine candidate, a second group received a commercially licensed inactivated influenza vaccine by intramuscular injection, and a third group received placebo. Three months following immunization, volunteers were challenged (deliberate experimental administration) with live H1N1 (A/H1N1 pdm09) influenza virus by intranasal administration. The placebo group served as the control group to determine how many unvaccinated volunteers became infected and how severe their influenza symptoms became. Data from our vaccine candidate group and the commercially licensed inactivated vaccine group were compared to placebo to determine each vaccine's efficacy in this challenge study. Importantly, the two vaccines were also compared head-to-head. The goal of the study is to compare the efficacy of our vaccine to protect volunteers from illness caused by H1N1 influenza challenge, compared to both the injectable vaccine and placebo three months after immunization.

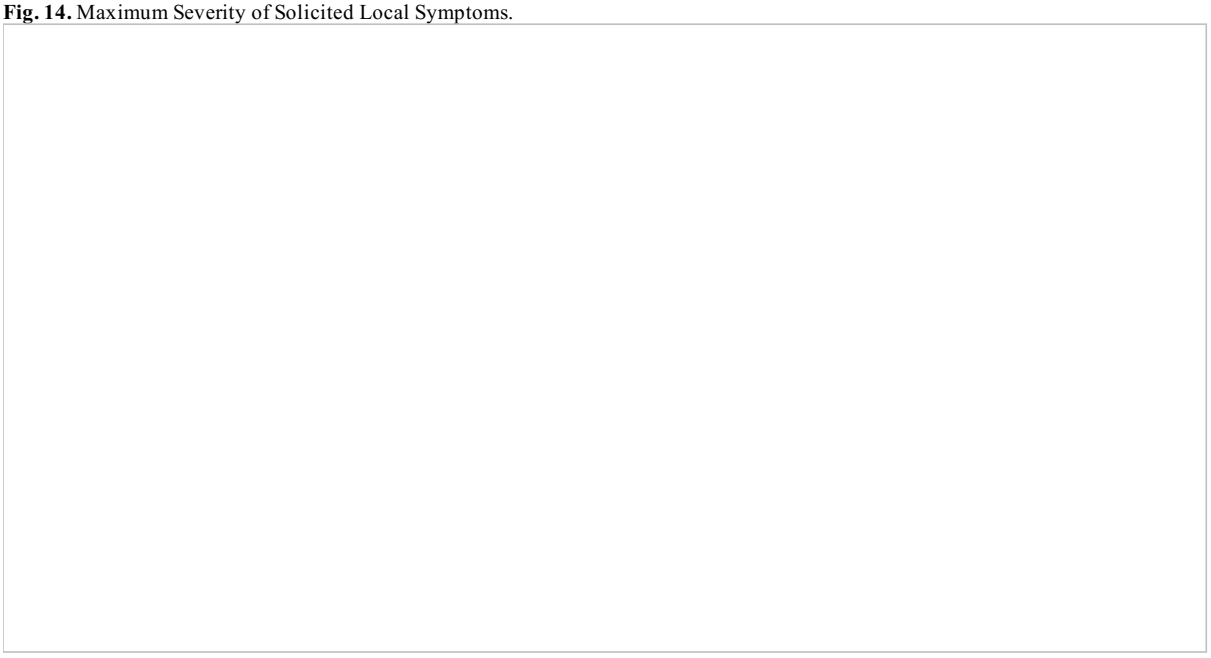
***Clinical Trial Results VXA-CHAL-201***

The Phase 2 challenge study was enrolled during 2016 and 2017. During this time, 179 subjects that cleared the screening requirements were randomized to receive a single dose of our tablet vaccine, the commercial injectable vaccine, or placebo. Of these 179 subjects, 143 subjects were subsequently challenged with live H1N1 influenza virus 90 to 120 days months after dosing.

- ***Safety.*** The side effects of the vaccines or placebo in the first seven days following administration were generally mild. In the first seven days following administration, the solicited adverse events (AEs) reported in the vaccine and placebo groups were mostly grade 1 in severity, and none were above grade 2. The most frequent solicited AE was headache in our tablet vaccine group (7%), injection site tenderness in the commercially licensed inactivated vaccine group (26%) and headache in the placebo group (19%). There were no serious adverse events and no new onsets of chronic illnesses related to our vaccine adjuvant recorded during the follow up period of the study. The graphs below show the distribution and severity over time of local and systemic (Figures 14 and 15) solicited AEs.

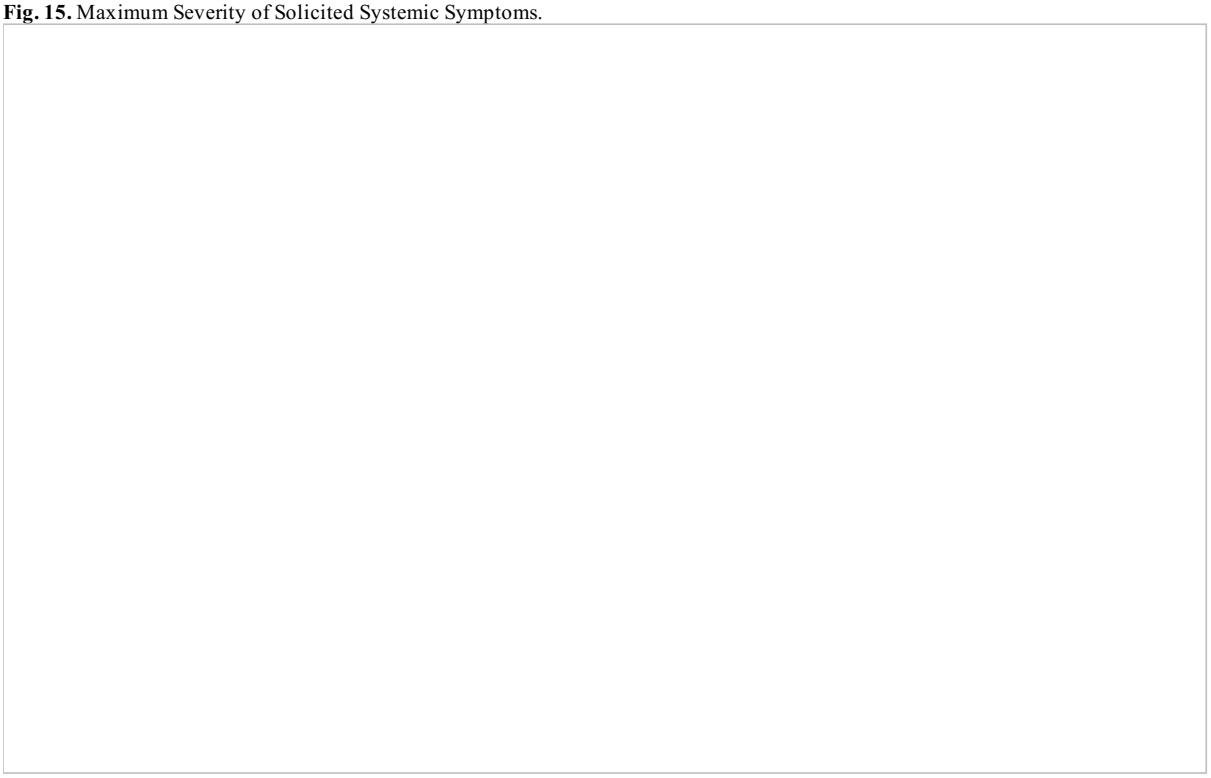
Table of Contents

**Fig. 14.** Maximum Severity of Solicited Local Symptoms.



*Caption. Solicited local symptoms were collected for seven days following immunization. The severity of solicited symptoms is indicated for each treatment group over time. All events were mild.*

**Fig. 15.** Maximum Severity of Solicited Systemic Symptoms.



*Caption. Solicited systemic symptoms were collected for seven days following immunization. The severity of solicited symptoms is indicated for each treatment group over time.*

***Efficacy – Reduction of PCR Confirmed Influenza Illness.***

The primary efficacy objective was to determine vaccine efficacy of our tablet vaccine following the challenge with the wild-type influenza A H1 virus strain (A/H1N1 pdm09). The primary efficacy endpoint was illness. The illness rate was 29% for our tablet vaccine, 35% for the commercial inactivated influenza vaccine, and 48% for subjects in the placebo group. Our tablet vaccine had a lower rate of illness than the commercial vaccine (-6% difference in illness rate in favor of our vaccine), although given the small size of the study, these differences were not statistically significant. Similarly, the difference in illness rates

between our tablet vaccine and placebo (-19.1%) and the commercial injected vaccine and placebo (-13.2%) trended toward protection but were not statistically significant. These results suggest that our vaccine is no worse, and trended better than the commercial vaccine for protection. The ability to show clinical efficacy in humans is a major step forward for our oral influenza product. These results are summarized in the table below.

**Table 6.** H1 Influenza Phase 2 Challenge Study: Illness Rates*.

| VAXART | | Commercial | | VAXART-Commercial | Placebo | |
|---|---|---|---|---|---|---|
| n | % (95% CI) | n | % (95% CI) | Rate Difference (95% CI) | n | % (95% CI) |
| 58 | 29.3 (18.1, 42.7) | 54 | 35.2 (22.7, 49.4) | -5.9 (-24.3, 12.5) | 31 | 48.4 (30.2, 66.9) |

**Illness was defined as a combination of symptoms reported on a patient reported outcome tool (Flu-PRO™) and quantitative reverse transcriptase polymerase chain reaction (qRT-PCR) detectable shed influenza virus.*

***Efficacy – Flu-PRO symptom Scores***

There were no statistically significant differences between the commercial inactivated influenza vaccine and our tablet vaccine for the Flu-PRO questionnaire, a validated patient recorded outcome tool used in influenza clinical trials in the community. However, our vaccine trended lower for overall symptom severity. Subjects in the VXA-A1.1 group showed a lower overall median Flu-PRO score (2.0 [0, 72]) than the QIV group (5.0 [0, 59]) or the placebo group (5.0 [0, 52]).

***Efficacy – Shedding***

Shedding represents influenza virus that is detected in nasal swabs post infection and is representative of viral infection and replication. In the study, 44.8% of subjects in VXA-A1.1 had at least one day positive for shedding, versus the commercial injected vaccine where 53.7% were positive for shedding and where 71.0% of placebo subjects were positive for shedding. There were no statistically significant differences observed between our tablet vaccine and the commercial inactivated influenza vaccine for viral shedding area under the curve (AUC). However, AUC was calculated using a standard logarithmic trapezoidal method and included only detectable shedding during the first 5 days of the duration of shedding, with subjects removed from the analysis that didn't shed influenza for 5 days (a zero value cannot be used in log calculations and integrated). This may have led to an underestimate of the effect on viral shedding for the two vaccines relative to placebo. Therefore, in order to better determine the effect of the vaccines on shedding, an alternative method was used in which volunteers were defined as infected if they had detectable viral shedding at any time 36 hours after challenge. This approach eliminated possible issues related to calculations (log calculations of zero values) and of large doses of challenge virus (first 36 hours might be pass through rather than replicating influenza). In a Bayesian analysis, both vaccines significantly reduced the probability of shedding relative to placebo (Bayesian posterior p=0.001 for our tablet vaccine and p=0.009 for the commercial inactivated influenza vaccine). There is also trend toward greater efficacy for our vaccine with an ~80% posterior probability (Table 7).

**Table 7.** H1 Influenza Phase 2 Challenge Study: Infection Rates*.

| Treatment Arm | N | Number Infected | Percent (95% CI) | Posterior P |
|---|---|---|---|---|
| Placebo | 31 | 22 | 71% (55-85%) | - |
| Commercial | 54 | 24 | 44% (32-58%) | 0.009 |
| Vaxart Vaccine | 58 | 21 | 36% (24-49%) | 0.001 |

**Infection was defined as any positive quantitative reverse transcriptase polymerase chain reaction (qRT-PCR) detectable shed influenza virus on any day after 36 hours from viral challenge. In a Bayesian analysis, both vaccines provide a statistically significant protection against infection. There is also trend toward greater efficacy for our vaccine with an ~80% posterior probability.*

***Immunogenicity***

***HAI responses.*** HAI measures the ability of serum antibodies that can disrupt binding of influenza virus to red blood cells. Historically, HAI correlates to protection for injected influenza vaccines. HAI responses were measured 30 days following immunization to determine the number and percentage of volunteers that seroconverted. In our tablet vaccine group, 32% of volunteers achieved seroconversion. In the commercial inactivated influenza vaccine group 84% of volunteers achieved HAI seroconversion at 30 days post vaccination. This difference was statistically significant ($P < 0.001$, Fisher's Exact test). There were no subjects in the placebo group who achieved seroconversion at 30 days post vaccination. Since 32% of subjects seroconverted in the Vaxart tablet vaccine group achieved HAI seroconversion, but 71% of subjects were protected from illness following influenza challenge, HAI seroconversion appeared not to be a reliable indicator of protection for the Vaxart vaccine. The table below summarizes the HAI data. The GMT, GMFR, percentage of volunteers who had a 4-fold rise in their HAI and the percentage of subjects who seroconverted are reported.

**Table 8.** Hemagglutination Antibody Inhibition (HAI) Geometric Mean Titer (GMT) and Geometric Mean Fold Rise (GMFR) Results Post Dosing with 95% Confidence Intervals by Strain, Study Day and Treatment Group.

| Full Analysis Set - Vaccination Phase | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Baseline (Pre-Dosing) | | 30 Days Post Dosing | | | | |
| Treatment Group | N | GMT (95% CI) | N | GMT (95% CI) | GMFR (95% CI) | % 4-Fold Rise (95% CI) | % Seroconversion (95% CI) |
| **Strain: A/California/7/2009** | | | | | | | |
| Vaxart Tablet Vaccine | 70 | 11.13 (9.55, 12.96) | 69 | 29.99 (23.72, 37.93) | 2.72 (2.18, 3.39) | 36.2 (25.0, 48.7) | 31.9 (21.2, 44.2) |
| Commercial Inactivated Influenza Vaccine | 72 | 9.84 (8.33, 11.63) | 70 | 273.13 (182.15, 409.54) | 27.50 (19.44, 38.90) | 90.0 (80.5, 95.9) | 84.3 (73.6, 91.9) |
| Placebo | 35 | 10.49 (8.37, 13.15) | 35 | 10.40 (8.15, 13.29) | 0.99 (0.88, 1.11) | 0.0 (0.0, 10.0) | 0.0 (0.0, 10.0) |

***IgA Antibody Secreting Cells.*** B cells specific for influenza HA (IgA antibody secreting cells or IgA ASCs) were measured at baseline and 8 days following immunization in order to determine the B cell responses to the vaccines. At 8 days following vaccination, subjects in the commercial inactivated influenza vaccine group had significantly higher mean numbers of spots per $10^6$ cells ($p<0.001$, Wilcoxon test) and significantly higher percentages of subjects with greater than 8 spots per $10^6$ cells ($p<0.001$, Fisher exact). At Day 8, the commercial inactivated influenza vaccine group had mean spots 286 per $10^6$ cells compared to mean spots of 116 per $10^6$ cells for the Vaxart tablet vaccine. Additionally, the commercial inactivated influenza vaccine group had a 96% response rate compared to 71% in the Vaxart tablet vaccine group. The table below summarizes these data.

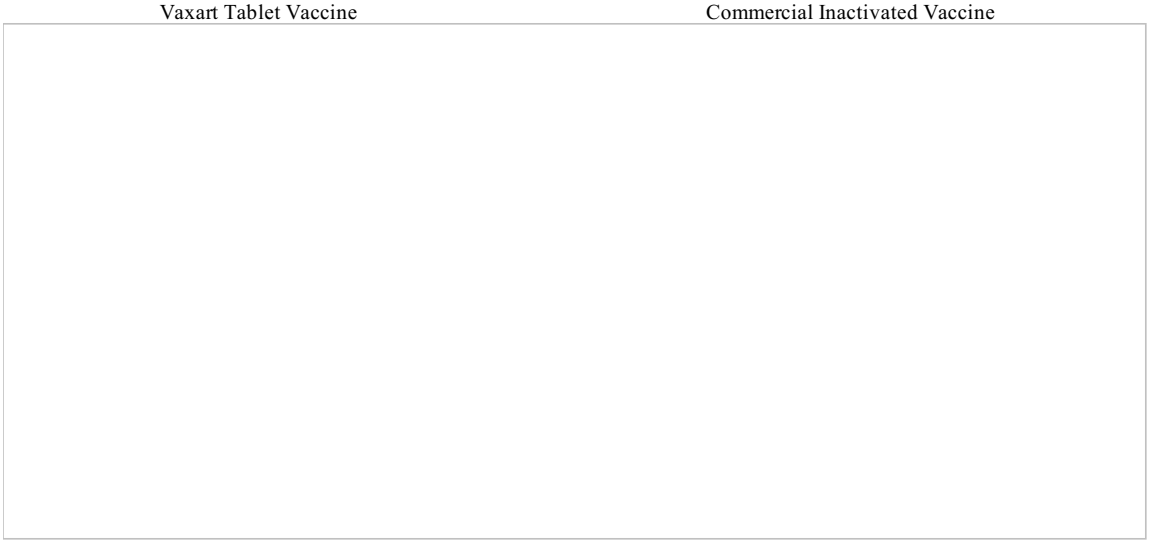
**Table 9.** ASC Response for IgA and IgG Assays by Study Day and Treatment Group – Vaccination Phase.

| | | Vaccination Phase | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Baseline (Pre-Dosing) | | | | Day 8 (Post-Dosing) | | | |
| Assay | Treatment Group | N | Mean | Median [Range] | At Least 8 Spots n (%) | N | Mean | Median [Range] | At Least 8 Spots n (%) |
| IgA ASC | Vaxart Tablet Vaccine | 70 | 2.0 | 0.0 [0, 18] | 6 (8.6) | 70 | 116.0 | 32.0 [0, 3251] | 50 (71.4) |
| | Commercial Inactivated Influenza Vaccine | 71 | 1.5 | 0.0 [0, 13] | 8 (11.3) | 71 | 286.4 | 153.0 [3, 1753] | 68 (95.8) |
| | Placebo | 36 | 2.8 | 0.0 [0, 26] | 6 (16.7) | 36 | 16.3 | 1.0 [0, 256] | 8 (22.2) |

***Correlation of IgA ASCs with Illness for the Vaxart Tablet Vaccine.*** As stated above the absolute mean number of ASCs was higher for the commercial inactivated influenza vaccine group (286 spots per $10^6$ cells) than for the Vaxart tablet vaccine (116 spots per $10^6$ cells). However, when a comparison was made between the two vaccines of the ratio of IgA ASCs in volunteers that were not ill divided by volunteers that were ill following challenge, the Vaxart tablet vaccine group had a ratio of 4.7 versus a ratio of 1.4 for the commercial injected vaccine. In a logistics fit model with illness versus non-illness as the outcome, and IgA ASC as the independent variable, the model showed that the Vaxart tablet vaccine IgA ASC could predict ill versus non-ill, but the logistics fit model for the commercial inactivated influenza vaccine could not ($p=0.0005$ for our vaccine, $p=0.3066$ for the commercial injected vaccine for whole logistic model). These data suggest that IgA ASC is important for protection against influenza for our oral vaccine, but not for injected commercial vaccines. These data also suggest that there are ***qualitative*** differences between B cells induced post immunization by different methods. We are actively exploring these qualitative differences.

**Fig. 16.** IgA ASCs Correlate with Illness for Vaxart Tablet Vaccine.

Vaxart Tablet Vaccine | Commercial Inactivated Vaccine



*Caption. Logistic fit regression analysis demonstrates a statistically significant fit for the Vaxart Tablet Vaccine for IgA ASCs and illness. The correlation between higher ASCs and a lower rate of illness is observed. The same model fit is not observed with the commercial inactivated vaccine.*

This work was funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority.

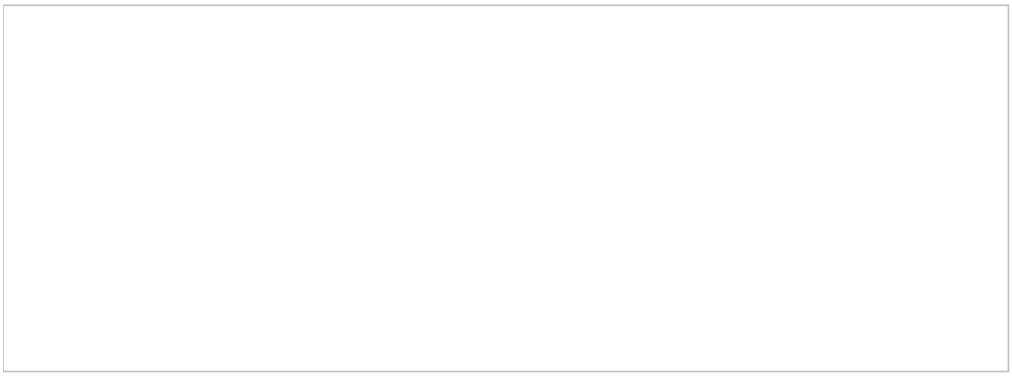
***Preclinical Results***

We have completed several animal challenge studies for influenza. In an H1N1 influenza challenge study, mice immunized orally with our tablet vaccine candidate were protected against sickness and death compared to unimmunized, control animals. Similarly, our oral H5N1 vaccine candidate protected ferrets and mice against a lethal avian influenza challenge compared to unimmunized animals when the vaccine construct expressed an avian influenza HA construct.

***Cross Protection of Vaxart Quadrivalent Seasonal Flu Vaccine against Avian Flu in Ferret Challenge Model***

A more recent ferret challenge experiment was completed in 2017 to compare an oral quadrivalent vaccine that we designed with the commercial vaccine Fluzone for protection against a virulent avian influenza strain. There are no components of seasonal influenza vaccines that are matched to the HA made by avian influenza virus, so the virus represents a severe case of vaccine mismatched to virus. Our quadrivalent vaccine was made by mixing four recombinant adenoviruses, each expressing a different HA that matches the HAs in the commercial vaccine, not the HA of the challenge. Two different doses were evaluated; the high dose was used at 1:10 of a Vaxart human dose (Vaxart Quad) and the low dose (Vaxart Quad Low) was used at 1:100 of the human dose. The Fluzone group (QIV) was given at 1:10 of the human dose to directly compare to the Vaxart quadrivalent high dose group. Vaxart animals and the negative control (PBS) animals were given vaccine delivered by endoscope. The QIV animals were intramuscularly injected. Animals were vaccinated on days 0 and 28. Animals were challenged on day 56 with approximately $10^{2.69}$ $TCID_{50}$/mL of wild type A/Vietnam/1203/2004 (A/VN). Results show that the Vaxart quadrivalent vaccines were able to protect against mismatched A/VN, trending better than Fluzone. The high dose group was able to protect all ferrets against death whereas the low dose Vaxart group protected 75% of ferrets.

**Fig. 17.** Survival in ferrets vaccinated with seasonal influenza and challenged with H5N1 Vietnam.



*Caption. The percent survival was measured for each group at each time point. The Vaxart Quad vaccine group were 100% protected against mismatched avian influenza over the 14 days that survival was assessed. The other groups were not as well protected.*

This work was funded in whole or in part with federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority.

***Seasonal Influenza Clinical Development Strategy and Pathway***

We aim to partner and/or to obtain funding from the U.S. federal government to finance the development and commercialization of our seasonal quadrivalent influenza oral tablet vaccine. In the future, we may also consider equity offerings and/or debt financings to fund the program.

***Our Human Papillomavirus (HPV) Therapeutic Vaccine Candidate***

In previous clinical studies with our H5 influenza vaccine candidate, we observed robust T-cell responses that appeared to compare favorably with published results of other flu vaccines, including an adjuvanted vaccine as well as an attenuated live viral vaccine. Specifically, our vaccine generated high levels of polyfunctional cytotoxic CD4 and CD8 cells, T-cells that are likely required to obtain a therapeutic benefit in chronic viral infection and cancer. It was based on these observations that we embarked on the development of our first therapeutic vaccine, targeting HPV -associated dysplasia and cervical cancer.

***Medical Need, Commercial Opportunity***

HPV is a family of more than 120 viruses which are extremely common globally. At least 13 HPV types are cancer-causing. HPV is primarily transmitted through sexual contact and infection is very prevalent following the onset of sexual activity. Nearly all cases of cervical cancer are attributable to HPV infection, with two HPV types – HPV16 and HPV18 – responsible for 70% of cervical cancers and precancerous cervical lesions. Cervical cancer is the fourth most common cancer in women worldwide, and about 13,000 new cases are diagnosed annually in the United States according to the National Cervical Cancer Coalition. Studies have indicated a high lifetime probability of any HPV infection by both men and women in the United States, with some estimates indicating at least 80% of women and men acquire HPV by age 45. The CDC estimates 80 million U.S. citizens are currently infected with HPV, representing 25% of the population, with about 14 million new infections per year. A report by BCC Research expects the global cervical cancer drug and diagnostic market to exceed $15 billion by 2018.

In women, many HPV infections of the cervix will spontaneously resolve and clear within 2-3 years, but women who have a persistent infection are at high risk of developing cellular abnormalities known as cervical intraepithelial neoplasia (CIN) which can progress to invasive cancer over time. More than 400,000 women are diagnosed with CIN annually in the United States, with an annual incidence estimate for CIN1 and CIN2/3 at 1.6 and 1.2 per 1,000 women, respectively.

There are currently no approved therapeutic vaccines to treat HPV infection. Current treatment options for women infected with HPV (see below) include monitoring CIN status, surgical procedures to remove affected tissue, and chemotherapeutic or radiation therapies to treat localized or metastatic cervical cancer. Thus, a medical need remains for a therapeutic vaccine to treat women presenting with CIN, or who have progressed to cervical cancer.

***Our HPV Therapeutic Vaccine Candidate***

Our plan is to develop a bivalent HPV vaccine against HPV 16 and 18, the strains responsible for approximately 70% of cases of cervical cancer. We plan to target the E6 and E7 gene products of each strain, which are the primary oncogenic proteins responsible for progression through the stages of CIN to invasive cervical cancer. In pre-clinical studies, we have demonstrated immunogenicity for both our HPV16 and our HPV18 vaccine candidates. Specifically, mice given our HPV16 or HPV18 vaccines induced T cell responses to HPV as measured by IFN gamma ELISPOT. In addition, our HPV16 vaccine has demonstrated tumor growth suppression as well as increased survival in a robust HPV tumor model in mice. We believe that our HPV vaccine has several advantages over current treatment options for both CIN and cervical cancer. Current treatment options for CIN are invasive and can lead to serious contraindications for pregnancy. In addition, surgical treatments for CIN do not treat the underlying HPV, but rather remove infected tissue. As a result, current CIN treatment options have a significant failure rate which can increase the risk for progression to cervical cancer. Our vaccines have demonstrated a favorable safety and tolerability profile in clinical subjects dosed to date. Current treatment options for cervical cancer, such as chemotherapy and radiation treatment, have multiple side effects such as hair loss, loss of appetite, and severe nausea.

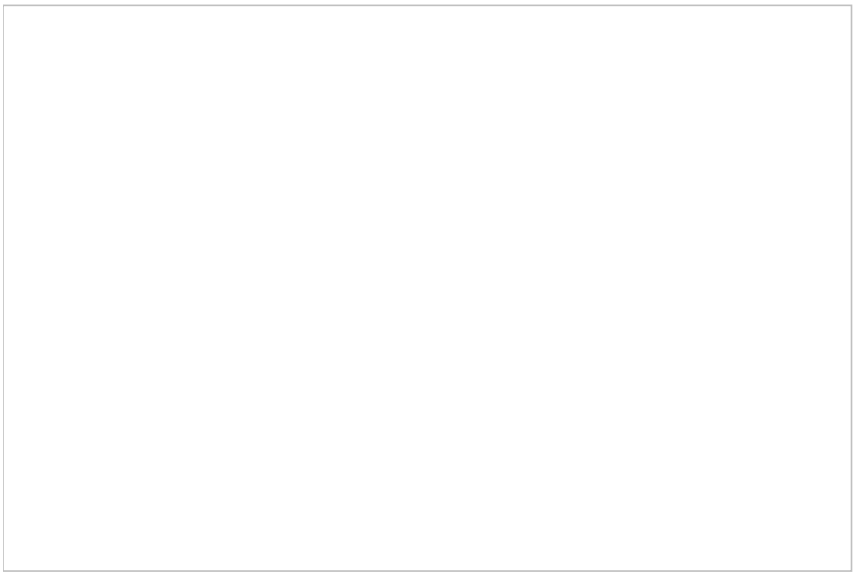
**T cells responses to HPV-16 can shrink solid tumors derived from transformed HPV**

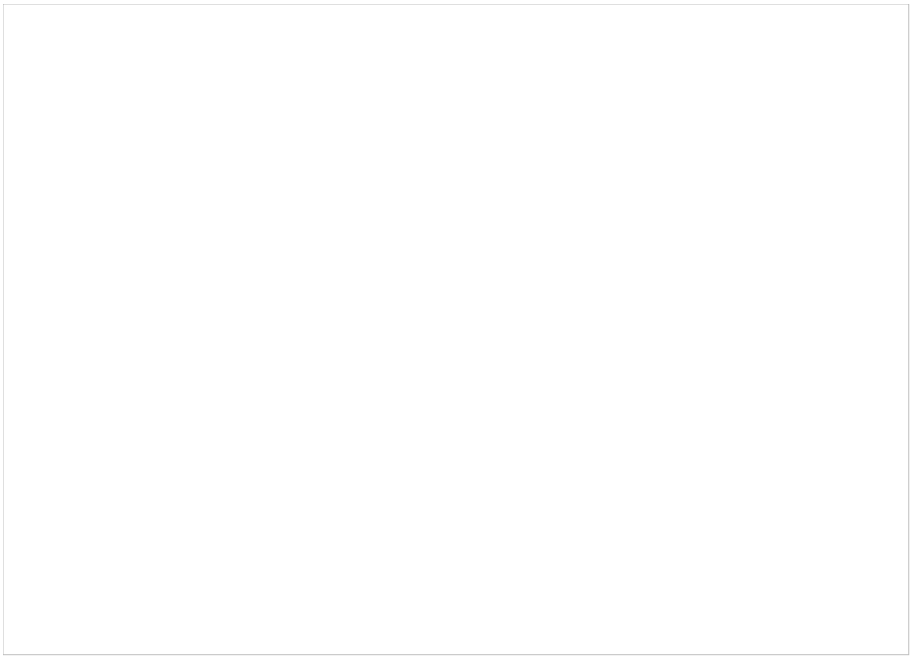
The ability of T cell responses to HPV-16 to produce a therapeutic response was tested in a solid tumor growth model. TC-1 cells (an HPV-16 transformed cell-line) were injected subcutaneously into the hind flank of B6 mice, and allowed to grow for several days before mice were immunized with vaccine or controls. In study 1, mice were immunized on days 7, 14, and 21. For groups 4 and 5, the vaccine expressed the HPV16 antigens E6/E7 (Ad-HPV). A checkpoint inhibitor (an antibody to PD-1) was used along with the vaccine in group 5, and an isotype control (Iso) to the checkpoint inhibitor was used in group 4. A recombinant rAd vector identical to Ad-HPV, but which doesn't express the HPV antigens (Ad-nr), was used in groups 1 or 2 to control for non-specific effects. Untreated animals were not given any vaccine.

The results in study 1 showed that Ad-HPV groups were able to the stop tumor growth, and actually shrink the tumor. This occurred whether the checkpoint inhibitor was used or not. The checkpoint inhibitor alone was not able to stop tumor progression, and eventually all these animals perished. Other control animals without Ad-HPV didn't survive as well. The use of the checkpoint inhibitor with the Ad-HPV vaccine trended slightly better for survival (10/10 versus 9/10 survived), but this was not significant.

In study 2, the TC-1 tumor was transplanted as before, but allowed to grow longer before immunization occurred. Immunizations occurred on days 13, 20, and 27. In this study, mice that received the Ad-HPV vaccine plus the checkpoint inhibitor were able to control the tumor, up through day 40 before a few mice started to perish. More than 70% of animals in this group survived through the end of the experiment on day 80. Ad-HPV immunized mice in the absence of the checkpoint inhibitor were also able to substantially control the tumor through 60 days (33 days after the last immunization), before several additional animals perished. No control groups in the absence of the Ad-HPV were able to control any of the tumors, and all mice perished before day 40.

**Fig. 18.** Small Tumor Vaccine Study.

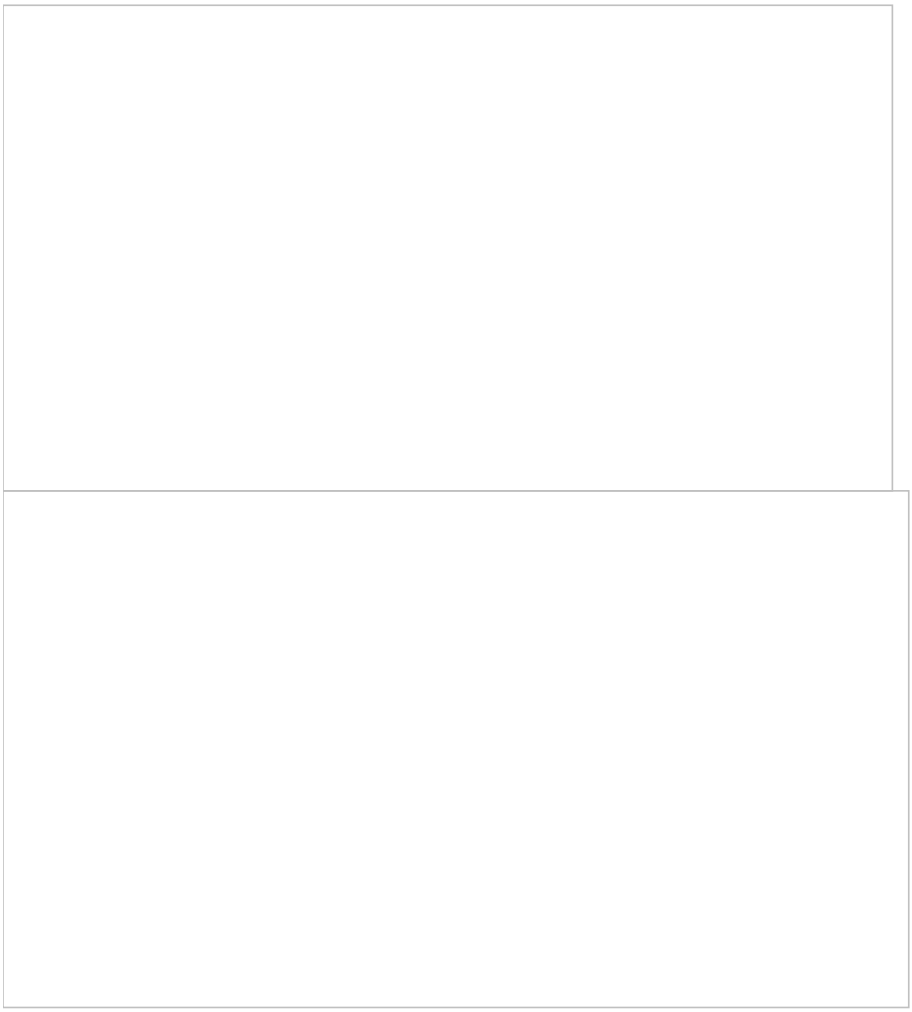




*Caption. In the small tumor vaccine study (Study 1), tumors were allowed to grow for 7 days before beginning the immunization schedule. Animals given the Vaxart HPV vaccine (Ad-HPV) were protected against tumor growth and survived better. This was the case whether or not a checkpoint inhibitor was used.*

Table of Contents

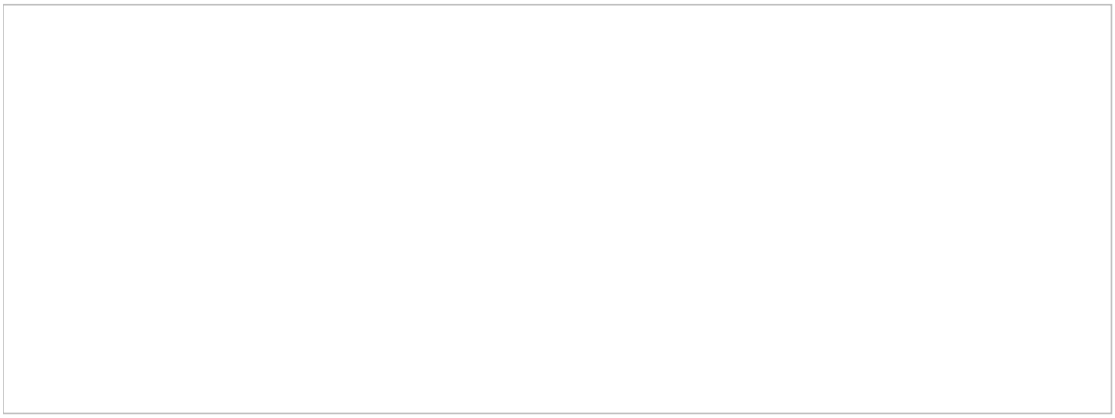
**Fig. 19.** Large Tumor Vaccine Study.



*Caption. In the large tumor vaccine study (Study 2), tumors were allowed to grow for 13 days before the vaccines were given. Again, animals given the Ad-HPV were better protected against tumor growth. The addition of the checkpoint inhibitor improved survival.*

The T cells induced post immunization in the tumor model were believed to traffic back to the solid tumor to attack and destroy the cancer cells. This was tested in an additional tumor model experiment. Tumors were transplanted as before, and immunizations were performed on days 13 and 21. Tumors were harvested from the experiment on day 24, and flow cytometry was used to enumerate the T cells infiltrating the tumors. The HPV16 vaccine groups (with either the checkpoint inhibitor or an isotype control antibody) had T cell infiltrates of both CD4 and CD8 positive T cells. The CD8 T cell numbers from the Ad-HPV groups were significantly better than control treated animals in terms of infiltrating lymphocytes. The CD4 T cells were significantly better in the Ad-HPV + checkpoint group, and trended higher in the Ad-HPV + isotype control group.

**Fig. 20.** The Ad-HPV vaccine induces T cells that migrate to the tumors.



*Caption. The number of CD4 and CD8 T cells found within the tumor were analyzed by flow cytometry. The Ad-HPV groups were found to elicit T cells that*

*transited to the tumor, with the Ad-HPV plus checkpoint inhibitor creating slightly more T cell transit than the Ad-HPV vaccine alone.*

**Near Term HPV Vaccine Development Strategy**

***Preclinical***

The next steps in the vaccine development are to complete the nonclinical studies, which may include a Good Laboratory Practices, GLP, toxicology study, to support an investigational new drug, or IND, filing for this vaccine. The exact nature of these studies will be determined in consultation with the FDA.

***Clinical***

We will propose to test the vaccine in subjects with cervical dysplasia related to HPV16 or HPV18, and to evaluate the ability of the vaccine to clear HPV infection, reduce the cervical dysplasia score, and induce T cells known to be important in the clearance of HPV. T cells will be measured by flow cytometry as well as by IFN-g ELISPOT. The primary endpoint will be safety and the secondary endpoint will be immunogenicity by examining T cell responses. Although clinical responses will be tracked, it is expected that the first study may not be powered to obtain statistically significant efficacy readouts.

**Other Indications**

We currently have preliminary data in animal models for indications such as RSV, Chikungunya, Hepatitis B and HSV-2.

**Manufacturing**

Manufacturing our oral tablet vaccines consists of two main stages, the production of bulk vaccine (drug substance), and the formulation and tableting thereof (drug product). Drug substance manufacturing consists primarily of the production and purification of the active ingredient. Bulk drug substance is then lyophilized, formulated and subsequently tableted and coated using a proprietary formulation and tableting process that we developed.

From 2012 through December of 2017, we relied on a third-party contract manufacturer, Lonza Houston, Inc. or Lonza Houston, to manufacture clinical bulk drug substance for our tablet vaccine candidates. During 2017 and early 2018, we developed our own bulk vaccine manufacturing process and then established a cGMP bulk manufacturing facility at our corporate headquarters in California. We believe having an in-house bulk facility provides a number of important strategic advantages, including control of our manufacturing schedule and enhanced integration of process development and cGMP manufacturing operations.

Our facility is fully operational and was used to make our norovirus GII.4 vaccine tablets and the norovirus GI.1 bulk vaccine lots that are scheduled to be processed and tableted in the first quarter of 2019. However, we have not yet achieved the productivity levels we initially projected and we continue to seek improvements in productivity. We are also making modifications to our purification process to further improve purity and yield.

Our facility and equipment is sized to support manufacturing of cGMP product for our Phase 1 and Phase 2a trials, but is not adequate to support larger Phase 2b and Phase 3 trials. Accordingly, we are exploring opportunities to establish a long-term relationship with an established CMO to develop large scale bulk vaccine production capabilities adequate to support larger trials and commercial product launch. We believe such a relationship would also allow us to access additional manufacturing expertise and further improve our manufacturing process.

From 2012 through December of 2017, we also contracted with Lonza Houston for the manufacture, labeling, packaging, storage and distribution of our drug product. The tablets used for our clinical studies to date, including the influenza A and B phase 1 studies, the norovirus phase 1 studies, the RSV phase 1 study and the H1 influenza phase 2 challenge study, as well as all placebo for those studies, were manufactured at Lonza Houston. During 2016, we established drug product manufacturing capabilities at our corporate headquarters and all drug product has been manufactured at our facility since then.

Our facility is licensed by the State of California Department of Public Health Food and Drug Branch to manufacture drug product for clinical trials.

We have limited experience with process development, and the manufacture, testing, quality release, storage and distribution of drug substance and drug product according to current Good Manufacturing Practices, or cGMP, and regulatory filings. The cGMP regulations include requirements relating to the organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. Our facility, and our third-party manufacturers, are subject to periodic inspections by FDA and local authorities, which include, but are not limited to procedures and operations used in the testing and manufacture of our vaccine candidates to assess our compliance with applicable regulations. If we or our third-part manufacturers fail to comply with statutory and regulatory requirements we and they could be subject to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. These actions could have a material adverse impact on the availability of our tablet vaccine candidates. Similar to contract manufactures, we have in the past encountered difficulties involving production yields, quality control and quality assurance, and if we are not able to produce drug product or drug substance in sufficient quantities are ability to conduct our clinical trials and commercialize our tablet vaccine candidates, if approved, will be impaired.

**Research and Development**

In the ordinary course of business, we enter into agreements with third parties, such as clinical research organizations, medical institutions, clinical investigators and contract laboratories, to conduct our clinical trials and aspects of our research and preclinical testing. These third parties provide project management and monitoring services and regulatory consulting and investigative services.

**Competition**

The biotechnology and pharmaceutical industries are characterized by intense competition to develop new technologies and proprietary products. While we believe that our proprietary tablet vaccine candidates provide competitive advantages, we face competition from many different sources, including biotechnology and pharmaceutical companies, academic institutions, government agencies, as well as public and private research institutions. Any products that we may commercialize will have to compete with existing products and therapies as well as new products and therapies that may become available in the future.

There are other organizations working to improve existing therapies, vaccines or delivery methods, or to develop new vaccines, therapies or delivery methods for their selected indications. Depending on how successful these efforts are, it is possible they may increase the barriers to adoption and success of our vaccine candidates, if approved.

We anticipate that we will face intense and increasing competition as new vaccines enter the market and advanced technologies become available. We expect any tablet or other oral delivery vaccine candidates that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, availability of therapeutics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we can obtain approval for our vaccine candidates, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

***Seasonal Influenza Vaccine Candidate***

We believe our seasonal influenza vaccine candidate will compete directly with approved vaccines in the market, which include non-recombinant and recombinant products that are administered via injection or intranasally. The major global non-recombinant injectable vaccine competitors include Astellas Pharma Inc., Abbott Laboratories, AstraZeneca UK Limited, Baxter International Inc., Research Foundation for Microbial Diseases of Osaka University, Seqirus-bioCSL Inc., GlaxoSmithKline plc, or GlaxoSmithKline, Sanofi S.A., or Sanofi, Pfizer Inc., and Takeda Pharmaceutical Company Limited, or Takeda. Non-recombinant intranasal competition includes MedImmune, Inc., or MedImmune, and potentially others. Recombinant injectable competitors include Sanofi, Medicago and Novavax, Inc., or Novavax. Many other groups are developing new or improved flu vaccine or delivery methods.

***Norovirus Vaccine Candidate***

There is currently no approved norovirus vaccine for sale globally. While we are not aware of all of our competitors' efforts, we believe that Takeda is developing a norovirus vaccine that would be delivered by injection.

***HPV Therapeutic Vaccine Candidate***

There is currently no approved HPV therapeutic vaccine for sale globally; however, a number of vaccine manufacturers, academic institutions and other organizations currently have, or have had, programs to develop such a vaccine. We believe that several companies are in various stages of developing an HPV therapeutic vaccine including Inovio, Advaxis, Genexine, and several others.

***Inavir***

Other anti influenza antivirals are marketed in Japan, including Tamiflu and Relenza. On February 23, 2018, Osaka-based drug maker Shionogi & Co gained marketing approval for Xofluza, a new drug to treat influenza in Japan. The drug was approved for use against type A and B influenza viruses and requires only a single dose regardless of age. Xofluza may gain significant market share from Inavir in Japan, substantially reducing the sales of Inavir. This would significantly decrease the royalty payments we receive from Daiichi Sankyo.

**Intellectual Property**

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to our business, including seeking, maintaining, and defending patent rights. We also rely on trade secrets relating to our platform and on know-how, continuing technological innovation to develop, strengthen and maintain our proprietary position in the vaccine field. In addition, we rely on regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions where available. We also utilize trademark protection for our company name and expect to do so for products and/or services as they are marketed.

Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing the valid enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our tablet vaccine candidates may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. With respect to company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of manufacturing the same.

We have developed numerous patents and patent applications and own substantial know-how and trade secrets related to our platform and tablet vaccine candidates.

- ***Vaccine Platform Technology***. As of December 31, 2018, we hold three U.S. patents with granted claims relating to our platform technology. Two of these U.S. patents include claims related to our seasonal influenza vaccine candidate. These patents will expire in 2027, or later if patent term extension applies. As of December 31, 2018, we hold more than 50 issued foreign patents and one pending foreign patent application related to our platform technology and/or our vaccine candidates. These patents will expire in 2027, or later if patent term extension applies.
- ***Tablet Vaccine Formulation***. We own considerable know-how and hold one Singapore patent and 16 pending applications in the United States and around the world related to our tablet vaccine formulation technology. This patent and any patents issuing from these applications will expire in 2035, or later if patent term extension applies.
- ***Influenza, Norovirus and RSV Vaccine Candidates***. As of December 31, 2018, we have filed 12 applications in the United States and around the world relating to our norovirus and RSV vaccine candidates. Any patents issuing from these applications will expire in 2036, or later if patent term extension applies. We have been issued 13 foreign patents related to our current H1N1 influenza vaccine candidate. These patents will expire in 2030,or later if patent term extension applies.
- ***Relenza***. As of December 31, 2018, we own one Japanese patent related to Relenza, which is exclusively licensed to GSK. This patent will expire in July 2019. All other Relenza patents have expired.

In addition to the above, we have established expertise and development capabilities focused in the areas of preclinical research and development, manufacturing and manufacturing process scale-up, quality control, quality assurance, regulatory affairs and clinical trial design and implementation. We believe that our focus and expertise will help us develop products based on our proprietary intellectual property.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing the non-provisional application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent.

The term of a patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration of a U.S. patent as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. When possible, depending upon the length of clinical trials and other factors involved in the filing of a new drug application, or NDA, we expect to apply for patent term extensions for patents covering our vaccine candidates and their methods of use.

**Trade Secrets**

We rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these procedures, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

**Government Regulation and Product Approval**

Federal, state and local government authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biological and pharmaceutical products such as those we are developing. Our vaccine candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

**U.S. Product Development Process**

In the United States, the FDA regulates pharmaceutical and biological products under the Federal Food, Drug and Cosmetic Act, Public Health Service Act, or PHSA, and implementing regulations. Products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a Biologics License Application, or BLA, for marketing approval that meets applicable requirements to ensure the continued safety, purity, and potency of the product that is the subject of the BLA based on results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced, to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA.

Before testing any biological vaccine candidate, including our tablet vaccine candidates, in humans, the vaccine candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the vaccine candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations composing the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1*. The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in subjects.
- *Phase 2*. The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3*. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to subjects.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

***U.S. Review and Approval Processes***

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The FDA may grant deferrals for submission of data, or full or partial waivers. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission, and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product.

Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

***Post-Approval Requirements***

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses, known as 'off-label' use, limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available products for off-label uses, if the physicians deem to be appropriate in their professional medical judgment, manufacturers may not market or promote such off-label uses.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our tablet vaccine candidates under development.

***Other U.S. Healthcare Laws and Compliance Requirements***

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, for instance the Office of Inspector General, the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the physician payment transparency laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and similar state laws, each as amended.

The federal anti-kickback statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The anti-kickback statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor, however, does not make the conduct per se illegal under the anti-kickback statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

Additionally, the intent standard under the anti-kickback statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, as discussed below.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal anti-kickback statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the HITECH Act, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Additionally, the Federal Physician Payments Sunshine Act under the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately, and completely the required information may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures". Certain states also mandate implementation of compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to healthcare providers and entities.

In order to distribute products commercially, we must also comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***Coverage, Pricing and Reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any tablet vaccine candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our tablet vaccine candidates, in addition to the costs required to obtain the FDA approvals. Our tablet vaccine candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Different pricing and reimbursement schemes exist in other countries. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any tablet vaccine candidates for which it receives regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect the pressure on healthcare pricing will continue to increase. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

US Healthcare Reform

We anticipate that current and future U.S. legislative healthcare reforms may result in additional downward pressure on the price that we receive for any approved product, if covered, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our tablet vaccine candidates. In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition and results of operations.

***Foreign Regulation***

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

**Employees**

Our management and scientific teams possess considerable experience in vaccine and anti-infective research, manufacturing, clinical development and regulatory matters. Our research team includes Ph.D.-level scientists with expertise in mucosal immunology, T cells, viral vectors and virology. As of December 31, 2018, we had 34 full-time employees. Of these, 26 employees are engaged in research and development and eight employees are engaged in finance, human resources, administration, business and general management. We have no collective bargaining agreements with our employees and we have not experienced any work stoppages. We consider our relations with our employees to be good.

## Item 1A. Risk Factors

*You should carefully consider the following risk factors, as well as the other information in this Annual Report on Form 10-K, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations", as well as our other public filings. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report on Form 10-K and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.*

*We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. This discussion highlights some of the risks that may affect future operating results. These are the risks and uncertainties we believe are most important to consider. We cannot be certain that we will successfully address these risks. If we are unable to address these risks, our business may not grow, our stock price may suffer and we may be unable to stay in business. Additional risks and uncertainties not presently known to us, which we currently deem immaterial or which are similar to those faced by other companies in our industry or business in general, may also impair our business operations.*

**Risks Related to Our Business, Financial Position and Capital Requirements**

***We have a limited operating history and have generated only limited product revenue.***

Even though we generate royalty revenue from our two commercialized influenza products, we are at an early stage in our clinical development process and have not yet successfully completed a large-scale, pivotal clinical trial, obtained marketing approval, manufactured our tablet vaccine or small-molecule antiviral drug candidates at commercial scale, or conducted sales and marketing activities that will be necessary to successfully commercialize our product candidates. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing product candidates.

Our ability to generate significant revenue and achieve and maintain profitability will depend upon our ability to successfully complete the development of our tablet vaccine candidates for the treatment of norovirus, seasonal influenza, respiratory syncytial virus, or RSV, cervical cancer and dysplasia caused by human papillomavirus, or HPV, and other infectious diseases, and to obtain the necessary regulatory approvals.

Even if we receive regulatory approval for the sale of any of our product candidates, we do not know when we will begin to generate significant revenue, if at all. Our ability to generate significant revenue depends on a number of factors, including our ability to:

- set an acceptable price for our product candidates and obtain coverage and adequate reimbursement from third-party payors;
- receive royalties on our products and product candidates including in connection with sales of Relenza and Inavir;
- establish sales, marketing, manufacturing and distribution systems;
- add operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future clinical development and commercialization efforts and operations as a public company;
- develop manufacturing capabilities for bulk materials and manufacture commercial quantities of our product candidates at acceptable cost levels;
- achieve broad market acceptance of our product candidates in the medical community and with third-party payors and consumers;
- attract and retain an experienced management and advisory team;
- launch commercial sales of our product candidates, whether alone or in collaboration with others; and
- maintain, expand and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with vaccine development and manufacturing, we are unable to predict the timing or amount of increased development expenses, or when we will be able to achieve or maintain profitability, if at all. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or the FDA, or comparable non-U.S. regulatory authorities, to perform studies or clinical trials in addition to those we currently anticipate. Even if our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of and the related commercial-scale manufacturing requirements for our product candidates. If we cannot successfully execute on any of the factors listed above, our business may not succeed.

***We have incurred significant losses since our inception and expect to continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.***

We have generated only limited product revenues and we expect to continue to incur substantial and increasing losses as we continue to develop our product candidates. Our product candidates have not been approved for marketing in the United States and may never receive such approval. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to generate significant revenue and achieve profitability is dependent on our ability to complete development, obtain necessary regulatory approvals, and have our product candidates manufactured and successfully marketed. We cannot be sure that we will be profitable even if we successfully commercialize one of our product candidates. If we do successfully obtain regulatory approval to market our tablet vaccine candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which regulatory approval is received, the number of competitors in such markets, the price at which we can offer our product candidates and whether we own the commercial rights for that territory. If the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of our product candidates, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we fail to become and remain profitable, the market price of our common stock and our ability to raise capital and continue operations will be adversely affected.

We expect research and development expenses to increase significantly for any of our tablet vaccines, including those for the prevention of norovirus, influenza and RSV infection, as well as those for the treatment of HPV related dysplasia and cancer, and any other chronic viral infections and cancer. In addition, even if we obtain regulatory approval, significant sales and marketing expenses will be required to commercialize the tablet vaccine candidates. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital. As of December 31, 2018, we had an accumulated deficit of $98.0 million.

***We recently completed the Merger with Aviragen and the failure to successfully integrate could adversely affect our future results.***

Our success will depend, in significant part, on our ability to integrate successfully and to manage successfully the challenges presented by the integration process in the Merger with Aviragen that was completed in February 2018. Potential difficulties that may be encountered in the integration process include the following:

- using our cash and assets efficiently to develop our business;
- appropriately managing our liabilities;
- potential unknown or currently unquantifiable liabilities associated with the Merger and our operations;
- difficulties in operating with a new management team as a public company; and
- performance shortfalls as a result of the diversion of the management's attention caused by integrating the companies' operations, in particular operating as a public company immediately post-merger with Aviragen.

***We are largely dependent on the success of our tablet vaccine for the prevention of norovirus infection which is still in early-stage clinical development, and if this tablet vaccine does not receive regulatory approval or is not successfully commercialized, our business may be harmed.***

None of our product candidates are in late-stage clinical development or approved for commercial sale and we may never be able to develop marketable tablet vaccine candidates. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our tablet vaccine candidate for norovirus. Accordingly, our business currently depends heavily on the successful development, regulatory approval and commercialization of our norovirus tablet vaccine. Our norovirus tablet vaccine may not receive regulatory approval or be successfully commercialized even if regulatory approval is received. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of tablet vaccine candidates are and will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market our norovirus tablet vaccine in the United States until we receive approval of a biologics license application, or BLA, from the FDA, or in any foreign countries until we receive the requisite approval from such countries. To date, we have only completed Phase 1 clinical trials for one of the two strains necessary for our bivalent norovirus tablet vaccine candidate. As a result, we have not submitted a BLA to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so for the foreseeable future. Obtaining approval of a BLA is an extensive, lengthy, expensive and inherently uncertain process, and the FDA may delay, limit or deny approval of our norovirus tablet vaccine for many reasons, including:

- We may not be able to demonstrate that our norovirus tablet vaccine is safe and effective to the satisfaction of the FDA;
- the FDA may not agree that the completed Phase 1 clinical trials of the norovirus vaccine satisfy the FDA's requirements and may require us to conduct additional testing;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of one or more of our clinical trials;
- the contract research organizations, or CROs, that we retain to conduct clinical trials may take actions outside of our control that materially and adversely impact our clinical trials;
- the FDA may not find the data from our preclinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of our tablet vaccines outweigh the safety risks;
- the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the FDA may not accept data generated at our clinical trial sites;
- if our NDA or BLA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a risk evaluation and mitigation strategy, or REMS, as a condition of approval;
- the FDA may identify deficiencies in our manufacturing processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

***We believe that there is substantial doubt about our ability to continue as a going concern.***

We have concluded that there is substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued. Our independent auditors included an explanatory paragraph in their report on our financial statements as of and for the year ended December 31, 2018, indicating that, because we have experienced losses and negative cash flows from operations and have an accumulated deficit and debt obligations, there is substantial doubt about our ability to continue as a going concern. We do not believe that this substantial doubt has been alleviated. As of December 31, 2018, we had $11.5 million of cash and cash equivalents. We believe these funds, along with our projected revenue, are sufficient to fund our operations into, but possibly not beyond, the second quarter of 2019. If we are unable to continue as a going concern, we may be forced to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

***We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our tablet vaccine candidates.***

We expect to spend substantial amounts to complete the development of, seek regulatory approvals for and commercialize our tablet vaccine candidates. Even with the cash acquired in the Merger and from the acquired royalty streams, we will require substantial additional capital to complete the development and potential commercialization of our tablet vaccine candidates for norovirus, seasonal influenza, RSV, HPV, and the development of other product candidates. If we are unable to raise capital or find appropriate partnering or licensing collaborations, when needed or on acceptable terms, we could be forced to delay, reduce or eliminate one or more of our development programs or any future commercialization efforts. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our development efforts.

Raising finance via the issuance of securities to the public generally entails filing documents with the SEC and, in the normal course of business, obtaining regulatory approval. The process is time-consuming and can result in delays in seeking potential investors. Further, the ongoing partial shutdown of the government means that SEC staff have been furloughed and are not available to review registration statements. This has already caused, and continues to cause, a delay in one potential source of financing via a registration statement that we filed with the SEC on December 27, 2018, and will continue to restrict our ability to raise finance via this and other potential alternatives until the SEC is fully staffed, and possibly beyond as a backlog is cleared.

As of December 31, 2018, we had $11.5 million of cash and cash equivalents. We believe these funds, along with our projected revenue, are sufficient to fund our operations under our current operating plan into, but possibly not beyond, the second quarter of 2019. Our estimate as to what we will be able to accomplish is based on assumptions that may prove to be inaccurate, and we could exhaust our available capital resources sooner than is currently expected. Because the length of time and activities associated with successful development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of our planned clinical trials;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the European Medicines Agency, or EMA, and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending potential intellectual property disputes, including any patent infringement actions brought by third parties against us now or in the future;
- the effect of competing technological and market developments;
- the cost of establishing sales, marketing and distribution capabilities in regions where we choose to commercialize our product candidates on our own; and
- the initiation, progress, timing and results of the commercialization of our product candidates, if approved, for commercial sale.

Additional funding may not be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or potentially discontinue operations.

***Raising additional funds by issuing securities may cause dilution to existing stockholders, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.***

We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, royalties, debt financings, strategic alliances and license and development agreements in connection with any collaborations. We do not currently have any committed external source of funds. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect our common stockholders' rights. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, creating liens, redeeming our stock or making investments.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, or through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties on acceptable terms, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

***The terms of our debt facility place restrictions on our operating and financial flexibility***.

In December 2016, we entered into a loan and security agreement, or the Loan Agreement, with Oxford Finance, LLC, or Oxford, as amended, under which we borrowed $5 million. Our outstanding debt facility with Oxford is collateralized by substantially all of our assets, except for intellectual property, which is subject to a negative pledge, and contains customary financial and operating covenants limiting our ability to transfer or dispose of assets, merge with or acquire other companies, make investments, pay dividends, incur additional indebtedness and liens and conduct transactions with affiliates. We therefore may not be able to engage in any of the foregoing transactions until our current debt obligations are paid in full or we obtain the consent from Oxford. Compliance with these covenants may limit our flexibility in operating our business and our ability to take actions that might be advantageous to us and our stockholders.

Under the Loan Agreement, an event of default will occur if, among other things:

- we fail to make payments when due under the Loan Agreement;
- we breach any of our covenants under the Loan Agreement, subject to specified cure periods with respect to certain breaches;
- there occurs an event that has a material adverse effect on:
  - our business, operations, properties, assets or financial condition;
  - our ability to perform or satisfy our obligations under the Loan Agreement as they become due or Oxford's ability to enforce its rights or remedies with respect to our obligations under the Loan Agreement; or
  - the collateral or liens securing our obligations under the Loan Agreement;
- we or our assets become subject to certain legal proceedings, such as bankruptcy or insolvency proceedings, or attachments;
- we are unable to pay our debts as they become due; or
- we default on certain contracts with third parties which would permit Oxford to accelerate the maturity of such indebtedness or that could have a material adverse effect on us.

We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness to Oxford at the time any such event of default occurs. In that case, we may be required to delay, limit, reduce or terminate our clinical development efforts or grant rights to develop and market product candidates to others that we would otherwise prefer to develop and market ourselves. Oxford could also exercise its rights as collateral agent to take possession and dispose of the collateral securing the Loan Agreement for its benefit as the secured lender. Our business would be harmed as a result of any of these events.

***Our stock price is expected to be volatile, and the market price of our common stock has fallen since the Merger.***

The market price of our common stock has been subject to significant fluctuations following the Merger. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that cause the market price of our common stock to fluctuate include:

- our ability to develop product candidates and conduct clinical trials that demonstrate our product candidates are safe and effective;
- our ability to negotiate and receive royalty payments on the sales of our product candidates including Relenza and Inavir;
- our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates to demonstrate safety and efficacy, receive regulatory approval and achieve commercial success;
- failure to maintain our existing third-party license, manufacturing and supply agreements;
- our failure, or that of our licensors, to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our product candidates;
- any inability to obtain adequate supply of product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new or competing products by our competitors;
- failure to meet or exceed financial and development projections that we may provide to the public;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain intellectual property protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including intellectual property or stockholder litigation;
- if securities or industry analysts do not publish research or reports about us, or if they issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by our existing stockholders in the future;
- trading volume of our common stock;
- adverse publicity relating to our markets generally, including with respect to other products and potential products in such markets;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our operations, financial performance and reputation.

***We do not anticipate that we will pay any cash dividends in the foreseeable future.***

The current expectation is that we will retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain, if any, for our stockholders.

***Future sales of shares by existing stockholders could cause our stock price to decline.***

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of December 31, 2018, our officers, directors and their affiliate entities held 3.1 million shares of our common stock. Sales of a substantial number of shares of our common stock in the public market, or the perception that the sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

***One stockholder owns a significant percentage of our stock and, together with our management, will be able to exert significant control over matters subject to stockholder approval.***

As of December 31, 2018, entities affiliated with Care Capital, a venture capital fund, owned 39.2% of our common stock, and Care Capital together with our executive officers and directors owned 44.2% of our common stock. Therefore, these stockholders may be able to determine all matters requiring stockholder approval, and the entities affiliated with Care Capital alone will have significant ability to influence decisions through their ownership position. For example, this concentration of ownership may enable a small number of stockholders to influence or control elections of directors, amendments to our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction.

***Because the Merger resulted in an ownership change under Section 382 of the Code for Aviragen, pre-merger U.S. net operating loss carryforwards and certain other tax attributes are subject to limitations.***

If a corporation undergoes an "ownership change" within the meaning of Section 382 of the Code, the corporation's U.S. net operating loss carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds 50% over a three-year period. Similar rules may apply under state and foreign tax laws. The Merger resulted in an ownership change for Aviragen, and probably Vaxart; accordingly, Aviragen's U.S. net operating loss carryforwards and certain other tax attributes are subject to limitations on their use. Annual usage may be restricted to 1.97% of Aviragen's value on February 13, 2018. Additional ownership changes in the future could result in additional limitations on the combined organization's net operating loss carryforwards. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations.

***Changes in tax laws and regulations or in our operations may impact our effective tax rate and may adversely affect our business, financial condition and operating results.***

Changes in tax laws in any jurisdiction in which we operate, or adverse outcomes from any tax audits that we may be subject to in any such jurisdictions, could result in an unfavorable change in our effective tax rate in the future, which could adversely affect our business, financial condition, and operating results.

***Anti-takeover provisions under Delaware law could make an acquisition more difficult and may prevent attempts by our stockholders to replace or remove our management.***

Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of the outstanding company voting stock from merging or combining with the company. Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer was considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of management.

***If we fail to obtain or maintain adequate reimbursement and insurance coverage for our product candidates, our ability to generate significant revenue could be limited.***

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only on a limited basis, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain adequate pricing that will allow us to realize a sufficient return on our investment.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries may cause us to price our product candidates on less favorable terms that we currently anticipate. In many countries, particularly the countries of the European Union, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the level of reimbursement for our products is likely to be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market.

***Our future success depends on our ability to retain executive officers and attract, retain and motivate qualified personnel.***

We are highly dependent on our executive officers and the other principal members of the executive and scientific teams, particularly our President and Chief Executive Officer, Wouter W. Latour and our Chief Scientific Officer, Sean N. Tucker. The employment of our executive officers is at-will and our executive officers may terminate their employment at any time. The loss of the services of any of our senior executive officers could impede the achievement of our research, development and commercialization objectives. We do not maintain “key person” insurance for any executive officer or employee.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel is also critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our industry has experienced an increasing rate of turnover of management and scientific personnel in recent years. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in devising our research and development and commercialization strategy. Our consultants and advisors may be employed by third parties and have commitments under consulting or advisory contracts with other entities that may limit their availability to advance our strategic objectives. If any of these advisors or consultants can no longer dedicate a sufficient amount of time to us, our business may be harmed.

***We will need to expand our organization, and may experience difficulties in managing this growth, which could disrupt operations.***

Our future financial performance and our ability to commercialize our product candidates, continue to earn royalties and compete effectively will depend, in part, on our ability to effectively manage any future growth. As of December 31, 2018, we had 34 full-time employees. We expect to hire additional employees for our managerial, clinical, scientific and engineering, operational, manufacturing, sales and marketing teams. We may have operational difficulties in connection with identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our product candidates. If we are unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy.

Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than us. They may also provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates and consultants than what we are able to offer. If we are unable to continue to attract and retain high-quality personnel and consultants, the rate and success at which we can select and develop our product candidates and our business will be limited.

***Our employees, independent contractors, principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.***

We are exposed to the risk that our employees and contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies, manufacturing standards, federal and state healthcare fraud and abuse and health regulatory laws and other similar foreign fraudulent misconduct laws, or laws that require the true, complete and accurate reporting of financial information or data. Misconduct by these parties may also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***Our business and operations would suffer in the event of system failures.***

Our computer systems and those of our service providers, including our CROs, are vulnerable to damage from computer viruses, unauthorized access, natural disasters (including earthquakes), terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our or their operations, it could result in a material disruption of our development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

***We have identified a material weakness in our internal control over financial reporting, and if we are unable to maintain proper and effective internal controls over financial reporting, the accuracy and timeliness of our financial reporting may be adversely affected.***

In connection with the audits of our financial statements for each of the years ended December 31, 2015 through 2018, our management and our independent auditors identified a material weakness in our internal control over financial reporting. A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness relates to us lacking consistent processes to appropriately perform effective and timely review of account reconciliations and non-routine transactions.

We have already taken steps to remediate this material weakness. We have increased the depth and experience within our accounting and finance organization, in part by hiring a Corporate Controller and an Associate Director of SEC Reporting. We are also designing and implementing improved processes and internal controls. However, our efforts to remediate this material weakness may not be effective or prevent any future material weakness or significant deficiency in our internal control over financial reporting. If our efforts are not successful, or other material weaknesses or control deficiencies occur in the future, we may be unable to report our financial results accurately on a timely basis, which could cause our reported financial results to be materially misstated and result in the loss of investor confidence and cause the market price of our common stock to decline.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a quarterly report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our independent registered public accounting firm will be required to attest annually to the effectiveness of our internal control over financial reporting in the future should our public float exceed $75 million. We are required to disclose changes made in our internal control over financial reporting on a quarterly basis.

***We are incurring significant additional costs and demands upon management as a result of complying with the laws and regulations affecting public companies.***

We incur significant legal, accounting and other expenses associated with public company reporting requirements. We also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the SEC and The Nasdaq Stock Market LLC. These rules and regulations impose significant legal and financial compliance costs and make some activities more time-consuming and costlier. For example, our management team includes certain executive officers who have not previously managed and operated a public company. These executive officers and other personnel need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations.

***We may be subject to securities litigation, which is expensive and could divert management attention.***

The market price of our common stock has been and may continue to be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert management's attention from other business concerns, which could seriously harm our business.

***If securities or industry analysts do not publish research, or publish inaccurate or unfavorable rating, about our business, our stock price and trading volume could decline.***

The trading market for our common stock is influenced by independent research and reports that securities or industry analysts publish about us or our business from time to time. At present, there are no analysts covering our stock, which means we have low visibility in the financial markets, which could cause a low trading volume, which would tend to cause our stock price to decline. There can be no assurance that analysts will cover our stock in the future or, if they do, provide favorable ratings. If any analysts who cover us downgrade our stock, change their opinion of our stock or disseminate negative information regarding our business, our share price may decline.

**Risks Related to Clinical Development, Regulatory Approval and Commercialization**

***If we fail to continue to develop and refine the formulations of our tablet vaccine candidates, we may not obtain regulatory approvals, and even if approved, the commercial acceptance of our tablet vaccine candidates would likely be limited.***

In our H1N1 influenza Phase 2 trial we used vaccine tablets that contained approximately 1.5 x $10^{10}$ IU of vaccine. Accordingly, subjects in this trial were required to take 7 tablets in a single setting to reach the aggregate dose of 1 x $10^{11}$ IU, the target dose for this trial. We believe that in order to fully capture the commercial success of our seasonal influenza vaccine candidate, we will need to continue to refine our formulation and develop influenza vaccine tablets that contain the desired dose for each vaccine strain in a single tablet, resulting in a vaccination regime of no more than four tablets. Increasing the potency of the vaccine tablets may affect the stability profile of the vaccine and we may not be able to reduce the vaccination regime for an influenza strain to a single tablet or combine the four influenza strains into one vaccine tablet. In addition, increasing the potency of the vaccine tablets or combining the influenza strains necessary to create a quadrivalent vaccine may adversely affect manufacturing yields and render such tablets too costly to manufacture at commercial scale. Our efforts to develop tablet vaccine candidates for norovirus and RSV face similar formulation challenges. If we are unable to further develop and refine the formulations of our tablet vaccine candidates, we may be unable to obtain regulatory approval from the FDA or other regulatory authorities, and even if approved, the commercial acceptance of our tablet vaccine candidates would likely be limited.

***Clinical trials are very expensive, time-consuming, difficult to design and implement and involve an uncertain outcome, and if they fail to demonstrate safety and efficacy to the satisfaction of the FDA, or similar regulatory authorities, we will be unable to commercialize our tablet vaccine candidates.***

Our tablet vaccine candidates for norovirus and seasonal influenza are still in early-stage clinical development. Both will require extensive additional clinical testing before we are prepared to submit a BLA for regulatory approval for either indication or for any other treatment regime. We cannot predict with any certainty if or when we might submit a BLA for regulatory approval for any of our tablet vaccine candidates, which are currently in clinical development, or whether any such BLAs will be approved by the FDA. Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. For instance, the FDA may not agree with our proposed endpoints for any clinical trial we propose, which may delay the commencement of our clinical trials. The clinical trial process is also time-consuming. We estimate that the clinical trials we need to conduct to be in a position to submit BLAs for our tablet vaccine candidates for seasonal influenza, norovirus and RSV will take several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Our vaccine candidates in the later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Also, the results of early clinical trials of the tablet vaccine candidates for seasonal influenza, norovirus and RSV may not be predictive of the results of subsequent clinical trials. Furthermore, the FDA may impose additional requirements to conduct preclinical studies to advance the HPV therapeutic vaccine candidates which could delay initiation of Phase 1 studies. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

Moreover, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their vaccine candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Success in preclinical testing and early clinical trials does not ensure that later clinical trials, which involve many more subjects and, for influenza, all four strains rather than the one strain we have studied in Phase 1 clinical trials to date and the results of later clinical trials may not replicate the results of prior clinical trials and preclinical testing.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our tablet vaccine candidates, including that:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our tablet vaccine candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- the number of subjects required for clinical trials of our tablet vaccine candidates may be larger than we anticipate; enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- Our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our tablet vaccine candidates may be greater than we anticipate; and
- the supply or quality of our tablet vaccine candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our tablet vaccine candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our tablet vaccine candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our tablet vaccine candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Product development costs will also increase if we experience delays in testing or in receiving marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our tablet vaccine candidates, could allow our competitors to bring products to market before we do, and could impair our ability to successfully commercialize our tablet vaccine candidates, any of which may harm our business and results of operations.

***Our platform includes a novel vaccine adjuvant and all of our current tablet vaccine candidates include this novel adjuvant, which may make it difficult for us to predict the time and cost of tablet vaccine development as well as the requirements the FDA or other regulatory agencies may impose to demonstrate the safety of the tablet vaccine candidates.***

Novel vaccine adjuvants, included in some of our tablet vaccine candidates, may pose an increased safety risk to patients. Adjuvants are compounds that are added to vaccine antigens to enhance the activation and improve immune response and efficacy of vaccines. Development of vaccines with novel adjuvants requires evaluation in larger numbers of patients prior to approval than would be typical for therapeutic drugs. Guidelines for evaluation of vaccines with novel adjuvants have been established by the FDA and other regulatory bodies and expert committees. Our current tablet vaccine candidates, including for norovirus, include a novel adjuvant, and future vaccine candidates may also include one or more novel vaccine adjuvants. Any vaccine, because of the presence of an adjuvant, may have side effects considered to pose too great a risk to patients to warrant approval of the vaccine. Traditionally, regulatory authorities have required extensive study of novel adjuvants because vaccines typically get administered to healthy populations, in particular infants, children and the elderly, rather than to people with disease. Such extensive study has often included long-term monitoring of safety in large general populations that has at times exceeded 10,000 subjects. This contrasts with the few thousand subjects typically necessary for approval of novel therapeutics. To date, the FDA and other major regulatory agencies have only approved vaccines containing five adjuvants, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our tablet vaccine candidates in the United States or elsewhere.

***Enrollment and retention of subjects in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.***

We may encounter delays in enrolling, or be unable to enroll, a sufficient number of participants to complete any of our clinical trials. Once enrolled, we may be unable to retain a sufficient number of participants to complete any of our trials. Late-stage clinical trials of our tablet vaccine candidate for norovirus, in particular, will require the enrollment and retention of large numbers of subjects. Subject enrollment and retention in clinical trials depends on many factors, including the size of the subject population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of subjects to clinical sites and the eligibility criteria for the study. Further, since there are no reliable animal models to norovirus infection, human challenge studies have been used to understand viral activity and possible immune correlates that prevent infection making trials costlier than animal-based studies.

Furthermore, any negative results we may report in clinical trials of our tablet vaccine candidates may make it difficult or impossible to recruit and retain participants in other clinical trials of that same tablet vaccine candidate. Delays or failures in planned subject enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our tablet vaccine candidates, or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance in compliance with applicable regulations. Enforcement actions brought against these third parties may cause further delays and expenses related to our clinical development programs.

***We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.***

Vaccine development is highly competitive and subject to rapid and significant technological advancements. We face competition from various sources, including larger and better funded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as academic institutions, governmental agencies and public and private research institutions. In particular, our influenza vaccine candidate would compete with products that are available and have gained market acceptance as the standard treatment protocol. Further, it is likely that additional drugs or other treatments will become available in the future for the treatment of the diseases we are targeting.

For tablet vaccines, we face competition from approved vaccines, against which new tablet vaccines must demonstrate compelling advantages in efficacy, convenience, tolerability and safety, and from competitors working to patent, discover, develop or commercialize medicines before we can do the same with tablet vaccines.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of products for the treatment of diseases, as well as in obtaining regulatory approvals of those products in the United States and in foreign countries. Our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drugs that are more effective or less costly than any tablet vaccine candidate that we may develop.

We will face competition from other drugs currently approved or that will be approved in the future for the treatment of the other infectious diseases we are currently targeting. Therefore, our ability to compete successfully will depend largely on our ability to:

- develop and commercialize tablet vaccine candidates that are superior to other vaccines in the market;
- demonstrate through our clinical trials that our tablet vaccine candidates are differentiated from existing and future therapies;
- attract qualified scientific, vaccine development and commercial personnel;
- obtain patent or other proprietary protection for our tablet vaccine candidates;
- obtain required regulatory approvals;

- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully develop and commercialize, independently or with collaborators, new tablet vaccine candidates.

The availability of our competitors' vaccines could limit the demand, and the price we are able to charge, for any tablet vaccine candidate we develop. The inability to compete with existing or subsequently introduced vaccines would have an adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make any of our tablet vaccine candidates less competitive. In addition, any new vaccine that competes with an approved vaccine must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving the FDA's approval for or commercializing medicines before we do, which would have an adverse impact on our business and results of operations.

The biotechnology and pharmaceutical industries are characterized by intense competition to develop new technologies and proprietary products. While we believe that our proprietary tablet vaccine candidates provide competitive advantages, we face competition from many different sources, including biotechnology and pharmaceutical companies, academic institutions, government agencies, as well as public and private research institutions. Any products that we may commercialize will have to compete with existing products and therapies as well as new products and therapies that may become available in the future.

There are other organizations working to improve existing therapies, vaccines or delivery methods, or to develop new vaccines, therapies or delivery methods for their selected indications. Depending on how successful these efforts are, it is possible they may increase the barriers to adoption and success of our vaccine candidates, if approved.

We anticipate that we will face intense and increasing competition as new vaccines enter the market and advanced technologies become available. We expect any tablet or other oral delivery vaccine candidates that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, availability of therapeutics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our vaccine candidates, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

We believe our seasonal influenza vaccine candidate will compete directly with approved vaccines in the market, which include non-recombinant and recombinant products that are administered via injection or intranasally. The major non-recombinant injectable vaccine competitors include Astellas Pharma Inc., Abbott Laboratories, AstraZeneca UK Limited, Baxter International Inc., Research Foundation for Microbial Diseases of Osaka University, Seqirus-bioCSL Inc., GlaxoSmithKline plc, or GlaxoSmithKline, Sanofi S.A., or Sanofi, Pfizer Inc., and Takeda Pharmaceutical Company Limited, or Takeda. Non-recombinant intranasal competition includes MedImmune, Inc., or MedImmune, and potentially others. Recombinant injectable competitors include Sanofi and Novavax, Inc., or Novavax. Many other groups are developing new or improved flu vaccine or delivery methods.

There is currently no approved norovirus vaccine for sale globally. While we are not aware of all of our competitors' efforts, we believe that Takeda is also developing a virus-like particle-based norovirus vaccine that would be delivered by injection.

There is currently no approved RSV vaccine for sale globally; however, a number of vaccine manufacturers, academic institutions and other organizations currently have, or have had, programs to develop such a vaccine. In addition, many other companies are developing products to prevent disease caused by RSV using a variety of technology platforms, including monoclonal antibodies, small molecule therapeutics, as well as various viral vector and VLP based vaccine technologies. While we are not aware of all of our competitors' efforts, we believe that several companies are in various stages of developing an RSV vaccine including GlaxoSmithKline, Johnson & Johnson, Bavarian Nordic, Astellas, MedImmune, Novavax, and Sanofi, as well as the National Institute of Allergy and Infectious Diseases, an institute under the U.S. National Institutes of Health, and possibly others.

There is currently no approved HPV therapeutic vaccine for sale globally; however, a number of vaccine manufacturers, academic institutions and other organizations currently have, or have had, programs to develop such a vaccine. We believe that several companies are in various stages of developing an HPV therapeutic vaccine including Inovio, Advaxis, Genexine, and possibly others.

***Our tablet vaccine candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.***

Adverse events caused by our tablet vaccine candidates could cause reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval. If an unacceptable frequency or severity of adverse events are reported in clinical trials for our tablet vaccine candidates, our ability to obtain regulatory approval for such tablet vaccine candidates may be negatively impacted.

Furthermore, if any of our tablet vaccines are approved and then cause serious or unexpected side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the tablet vaccine candidates or impose restrictions on their distribution or other risk management measures;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way our tablet vaccine candidates are administered or to conduct additional clinical trials;
- we could be sued and held liable for injuries sustained by patients;
- we could be subject to the Vaccine Injury Compensation Program;
- we could elect to discontinue the sale of our tablet vaccine candidates; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected tablet vaccine candidate and could substantially increase the costs of commercialization.

***If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, our tablet vaccine candidates, and our ability to generate significant revenue will be impaired.***

Our tablet vaccine and small-molecule antiviral candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a tablet vaccine candidate will prevent us from commercializing the tablet vaccine candidate. We have not received approval to market any of our tablet vaccine candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on CROs to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the tablet vaccine candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our tablet vaccine candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and elsewhere, is expensive, may take many years and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the tablet vaccine candidates involved. We cannot be sure that we will ever obtain any marketing approvals in any jurisdiction. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical or other studies, and clinical trials. In addition, varying interpretations of the data obtained from preclinical testing and clinical trials could delay, limit or prevent marketing approval of a tablet vaccine candidate. Additionally, any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

***Even if we obtain FDA approval in the United States, we may never obtain approval for or commercialize our tablet vaccine candidates in any other jurisdiction, which would limit our ability to realize each product's full market potential.***

In order to market any of our tablet vaccine candidates in a particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional tablet vaccine candidate testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our tablet vaccine candidates in those countries. We do not have any tablet vaccine candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any tablet vaccine candidate we develop will be unrealized.

***Even if we obtain regulatory approval, we will still face extensive ongoing regulatory requirements and our tablet vaccine candidates may face future development and regulatory difficulties.***

Any tablet vaccine candidate for which we obtain marketing approval, along with the manufacturing processes, post- approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such tablet vaccine candidate, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety, efficacy and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and current GCP requirements for any clinical trials that we conduct post-approval. Even if marketing approval of a tablet vaccine candidate is granted, the approval may be subject to limitations on the indicated uses for which the tablet vaccine candidates may be marketed or to the conditions of approval. If a tablet vaccine candidate receives marketing approval, the accompanying label may limit the approved use of that tablet vaccine, which could limit sales.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety and/or efficacy of our tablet vaccine candidates. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our tablet vaccine candidates for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our tablet vaccine candidates, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such tablet vaccine candidate;
- restrictions on the labeling or marketing of a tablet vaccine candidate;
- restrictions on tablet vaccine distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the tablet vaccine candidate from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;

- recall of such tablet vaccine candidate;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of such tablet vaccine candidate;
- tablet vaccine candidate seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change, and additional government regulations may be enacted, that could prevent, limit or delay regulatory approval of any of our tablet vaccine candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

***Even if our tablet vaccine candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.***

If our tablet vaccine candidates, including our vaccine for norovirus, receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If they do not achieve an adequate level of acceptance, we may not generate significant revenues and become profitable. The degree of market acceptance, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments;
- our ability to offer our tablet vaccine candidates for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the willingness of the medical community to offer customers our tablet vaccine candidate option in addition to, or in the place of, injectable vaccines;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our tablet vaccine together with other medications.

Because we expect sales of our tablet vaccine candidate for norovirus, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of this tablet vaccine to achieve market acceptance would harm our business and could require us to seek additional financing sooner than we would otherwise plan.

***If we fail to comply with state and federal healthcare regulatory laws, we could face substantial penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, and the curtailment of our operations, any of which could harm our business.***

Although we do not provide healthcare services or submit claims for third-party reimbursement, we are subject to healthcare fraud and abuse regulation and enforcement by federal and state governments, which could significantly impact our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal anti-kickback statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it;

- the civil False Claims Act, or FCA, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent; knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the criminal FCA, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal civil monetary penalties statute, which prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a Federal or state governmental program;
- the federal physician sunshine requirements under the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Further, the Affordable Care Act, among other things, amended the intent requirements of the federal anti-kickback statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Moreover, while we do not, and will not, submit claims and our customers will make the ultimate decision on how to submit claims, we may provide reimbursement guidance to our customers from time to time. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers. Compensation for some of these arrangements includes the provision of stock options. While we have worked to structure our arrangements to comply with applicable laws, because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who influence the ordering of and use our products to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

***Product liability lawsuits against us could cause us to incur substantial liabilities and could limit the commercialization of any tablet vaccine candidates we may develop.***

We face an inherent risk of product liability exposure related to the testing of our tablet vaccine candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop after approval. For instance, since our norovirus tablet challenge study is being conducted in healthy human volunteers, any adverse reactions could result in claims from these injuries and we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any tablet vaccine candidates that it may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend any related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue; and
- the inability to commercialize any products we may develop.

Although we maintain product liability insurance coverage in the amount of up to $5 million per claim and in the aggregate, it may not be adequate to cover all liabilities that we may incur. Additionally, seasonal influenza is a covered vaccine of the National Vaccine Injury Compensation Program, and our participation in that program may require time and resources that impede product uptake, if approved. We anticipate that we will need to increase our insurance coverage as we continue clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

***If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business.***

The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We currently have product liability insurance coverage for our ongoing clinical trials in the amount of $5 million. Further, we also require clinical research and manufacturing organizations that assist us in the conduct of our trials or manufacture materials used in these trials to carry product liability insurance against such claims. This insurance coverage may not protect us against any or all of the product liability claims that may be brought against us in the future. We may not be able to acquire or maintain adequate product liability insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect ourselves against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. In the event any of our product candidates are approved for sale by the FDA or similar regulatory authorities in other countries and commercialized, we may need to substantially increase the amount of our product liability coverage. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have an adverse effect on our business.

***If we are unable to establish sales, marketing and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing our tablet vaccine candidates, if approved.***

We do not have any infrastructure for the sales, marketing or distribution of our tablet vaccine candidates, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any tablet vaccine candidates that may be approved, it must build our sales, distribution, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. To achieve commercial success for any tablet vaccine candidates for which we have obtained marketing approval, we will need a sales and marketing organization. While we expect to partner our tablet vaccines for seasonal influenza and RSV, we expect to build a focused sales, distribution and marketing infrastructure to market our other tablet vaccine candidates in the United States, if approved. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any tablet vaccine candidate launch, which would adversely impact commercialization.

Factors that may inhibit our efforts to commercialize our tablet vaccine candidates on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to administer our tablet vaccines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We intend to pursue collaborative arrangements regarding the sale and marketing of our tablet vaccine candidates, if approved, for certain international markets; however, we may not be able to establish or maintain such collaborative arrangements and, if able to do so, our collaborators may not have effective sales. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If we are unable to build our own sales force in the United States or negotiate a collaborative relationship for the commercialization of our tablet vaccine candidates outside the United States we may be forced to delay the potential commercialization or reduce the scope of our sales and marketing activities. We could have to enter into arrangements with third parties at an earlier stage than we would otherwise choose and we may be required to relinquish rights to our intellectual property or otherwise agree to terms unfavorable to us, any of which may have an adverse effect on our business, operating results and prospects.

We may be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third-party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

***If we obtain approval to commercialize any tablet vaccine candidates outside of the United States, a variety of risks associated with international operations could harm our business.***

If our tablet vaccine candidates are approved for commercialization, we intend to enter into agreements with third parties to market them in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international operations or entering into international business relationships, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign reimbursement, pricing and insurance regimes;
- foreign taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential noncompliance with the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions;
- tablet vaccination shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union and many of the individual countries in Europe with which we will need to comply.

***Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of, and to commercialize, our tablet vaccine candidates and affect the prices we may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our tablet vaccine candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any tablet vaccine candidates for which it obtains marketing approval.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, collectively the Affordable Care Act, was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Although the full effect of the Affordable Care Act may not yet be fully understood, the law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs.

Moreover, the Drug Supply Chain Security Act imposes obligations on manufacturers of prescription drugs in finished dosage forms. We have not yet adopted the significant measures that will be required to comply with this law. We are not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare vaccines, which could result in reduced demand for our tablet vaccine candidates or additional pricing pressures.

***Government involvement may limit the commercial success of our tablet vaccine candidates for influenza.***

If an influenza outbreak occurs and is classified as a pandemic or large epidemic by public health authorities, it is possible that one or more government entities may take actions that directly or indirectly have the effect of abrogating some of our rights or opportunities. We have not manufactured a pandemic vaccine to date, but if we were to do so, the economic value of such a vaccine to us could be limited.

Various government entities, including the U.S. government, are offering incentives, grants and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against influenza, which may have the effect of increasing the number of competitors and/or providing advantages to known competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market share for our influenza vaccines.

In addition, current influenza vaccines are generally trivalent (containing three strains) or quadrivalent (containing four strains). If the FDA requires or recommends, changes in influenza vaccines, for example for a monovalent vaccine or for use of a strain that is not currently circulating in the human population, it is uncertain whether we will be able to produce or manufacture such a vaccine at commercially reasonable rates.

***The seasonal nature of our target indications, in particular influenza, and competition from new products may cause unpredictable royalty revenues from Relenza and Inavir and significant fluctuations in our operating results.***

Influenza is seasonal in nature with sales of current vaccines occurring primarily in the first and fourth quarters of the calendar year. In addition, outbreaks of norovirus and RSV typically occur in the winter season. This seasonal concentration of product sales could cause quarter-to-quarter operating results to vary widely and can exaggerate the consequences of revenues of any manufacturing or supply delays, any sudden loss of inventory, any inability to satisfy product demand, the inability to estimate the effect of returns and rebates, normal or unusual fluctuations in customer buying patterns, or of any unsuccessful sales or marketing strategies during the sales seasons.

We currently earn royalty revenue from the net sales of Relenza and Inavir, which are marketed by our licensees. Although the royalty rates paid to us by our licensees are fixed at a proportion of the licensees' net sales of these products, our periodic and annual revenues from these royalties have historically been variable and subject to fluctuation based on the seasonal incidence and severity of influenza. In addition, returns of products to our licensees that were sold in prior years are taken into account in the calculation of net sales for purposes of determining the royalty revenue we receive and the amount of such returns are generally unpredictable. Our licensees may encounter competition from new products entering the market, including generic copies of Relenza and Inavir, which could adversely affect our royalty income. The last patent related to Inavir is set to expire in December 2029 in Japan, at which time royalty revenue will cease. However, the patent covering the laninamivir octanoate compound expires in 2024, at which time generic competition may enter the market, potentially decreasing or eliminating the royalties received. On February 23, 2018, Osaka-based drug maker Shionogi & Co gained marketing approval for Xofluza, a new drug to treat influenza in Japan. The drug was approved for use against type A and B influenza viruses and requires only a single dose regardless of age. Xofluza may gain significant market share from Inavir in Japan, substantially reducing the sales of Inavir. This would significantly decrease the royalty payments we receive from Daiichi Sankyo.

In addition, most of our Relenza patents have expired and the only substantial remaining intellectual property related to the Relenza patent portfolio is scheduled to expire in July 2019 in Japan. Further, we sold a portion of our Inavir royalties to HealthCare Royalty Partners III, L.P., or HCRP, in April 2016. We cannot predict with any certainty what our royalty revenues are likely to be in any given year.

***If safety, tolerability, resistance, drug-drug interactions, competing products or efficacy concerns should arise with Relenza or Inavir, our future royalty revenue may be reduced, which would adversely affect our financial condition and business.***

We currently earn royalty revenue from Relenza and Inavir, which are marketed by our licensees. Data supporting the marketing approvals and forming the basis for the safety warnings in the product labels for these products were obtained in controlled clinical trials of limited duration in limited patient populations and, in some cases, from post-approval use. As these marketed products are used over longer periods of time and by more patients, some with underlying health problems or taking other medicines, new issues such as safety, tolerability, resistance or drug-drug interaction issues could arise, which may require our licensees to provide additional warnings or contraindications on their product labels, or otherwise narrow the approved indications. Further, additional information from ongoing research or clinical trials of these products that raise any doubts or concerns about their efficacy may arise, or competing products may be introduced and limit the market penetration of our product candidates. If serious safety, tolerability, resistance, drug-drug interaction, efficacy, competing products, or any other concerns or issues arise with respect to Relenza and Inavir, sales of these products could be impaired, limited or abandoned by our licensees or by regulatory authorities, in which case our royalty revenue would decrease.

***Our success depends largely upon our ability to advance our product candidates through the various stages of drug development. If we are unable to successfully advance or develop our product candidates, our business will be materially harmed.***

Even though we generate royalty revenue from our two commercialized influenza products, all of our remaining product candidates are in early stages of development and their commercial viability remains subject to the successful outcome of future preclinical studies, clinical trials, manufacturing processes, regulatory approvals and the risks generally inherent in the development of pharmaceutical product candidates. Failure to advance the development of one or more of our product candidates may have a material adverse effect on our business. For example, the Phase 2 trial of teslexivir, a product acquired through the merger with Aviragen, was costly and diverted resources from our other product candidates, did not achieve the primary efficacy endpoint. The long-term success of our business ultimately depends upon our ability to advance the development of our product candidates through preclinical studies and clinical trials, appropriately formulate and consistently manufacture them in accordance with strict specifications and regulations, obtain approval of our product candidates for sale by the FDA or similar regulatory authorities in other countries, and ultimately have our product candidates successfully commercialized, either by us or by a strategic partner or licensee. We cannot be sure that the results of our ongoing or future research, preclinical studies or clinical trials will support or justify the continued development of our product candidates, or that we will ultimately receive approval from the FDA, or similar regulatory authorities in other countries, to advance the development of our product candidates.

Our product candidates must satisfy rigorous regulatory standards of safety, efficacy and manufacturing before we can advance or complete their development and before they can be approved for sale by the FDA or similar regulatory authorities in other countries. To satisfy these standards, we must engage in expensive and lengthy studies and clinical trials, develop acceptable and cost-effective manufacturing processes, and obtain regulatory approval of our product candidates. Despite these efforts, our product candidates may not:

- demonstrate clinically meaningful therapeutic or other medical benefits as compared to a patient receiving no treatment or over existing drugs or other product candidates in development to treat the same patient population;
- be shown to be safe and effective in future preclinical studies or clinical trials;
- have the desired therapeutic or medical effects;
- be tolerable or free from undesirable or unexpected side effects;
- meet applicable regulatory standards;
- be capable of being appropriately formulated and manufactured in commercially suitable quantities or scale and at an acceptable cost; or

- be successfully commercialized, either by us or by our licensees or collaborators.

Even if we demonstrate favorable results in preclinical studies and early-stage clinical trials, we cannot be sure that the results of late-stage clinical trials will be sufficient to support the continued development of our product candidates. Many, if not most, companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, setbacks and failures in all stages of development, including late-stage clinical trials, even after achieving promising results in preclinical testing or early-stage clinical trials. Accordingly, results from completed preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results we may obtain in future late-stage trials. Furthermore, even if the data collected from preclinical studies and clinical trials involving any of our product candidates demonstrate a satisfactory safety, tolerability and efficacy profile, such results may not be sufficient to obtain regulatory approval from the FDA in the United States, or other similar regulatory agencies in other jurisdictions, which is required to market and sell the product.

***If the actual or perceived therapeutic benefits, or the safety or tolerability profile of any of our product candidates are not equal to or superior to other competing treatments approved for sale or in clinical development, we may terminate the development of any of our product candidates at any time, and our business prospects and potential profitability could be harmed.***

We are aware of a number of companies marketing or developing various classes of anti-infective product candidates or products for the treatment of patients infected with HPV and RSV that are either approved for sale or further advanced in clinical development than ours, such that their time to approval and commercialization may be shorter than that for our product candidates.

Effective treatments of RSV infections in pediatrics, the elderly, and the immunocompromised are very limited. Currently, only Virazole (ribavirin) is indicated for the treatment of hospitalized infants and young children with severe lower respiratory tract infections due to RSV. We are aware that the following compounds are under development to treat RSV infections: Gilead's presatovir, Johnson & Johnson's JJ-53718678 (ALS-8176), Ablynx's ALX-0171 and Ark Biosciences' AK0529. The only approved drug for the prevention of RSV infections in high risk infants is MedImmune's palivizumab (Synagis), a monoclonal antibody. There are several vaccines and antibody products designed to prevent RSV infections in clinical development. Among the clinical stage product candidates in development are Novavax's RSV F vaccine, GSK's GSK3003898A vaccine, GSK's GSK3389245A vaccine, Bavarian Nordic's BN RSV vaccine, MedImmune's MEDI ÄM2-2 vaccine and MedImmune's monoclonal antibody MEDI8897.

If at any time we believe that any of our product candidates may not provide meaningful or differentiated therapeutic benefits, perceived or real, equal to or better than our competitors' products or product candidates, or we believe that our product candidates may not have as favorable a safety or tolerability profile as potentially competitive compounds, we may delay or terminate the future development of any of our product candidates. We cannot provide any assurance that the future development of any of our product candidates will demonstrate any meaningful therapeutic benefits over potentially competitive compounds currently approved for sale or in development, or an acceptable safety or tolerability profile sufficient to justify their continued development.

***Our product candidates may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products, which may delay or preclude their development or regulatory approval or limit their use if ever approved.***

Throughout the drug development process, we must continually demonstrate the activity, safety and tolerability of our product candidates in order to obtain regulatory approval to further advance their clinical development, or to eventually market them. Even if our product candidates demonstrate adequate biologic activity and clear clinical benefit, any unacceptable side effects or adverse events, when administered alone or in the presence of other pharmaceutical products, may outweigh these potential benefits. We may observe adverse or serious adverse events or drug-drug interactions in preclinical studies or clinical trials of our product candidates, which could result in the delay or termination of their development, prevent regulatory approval, or limit their market acceptance if they are ultimately approved.

***If the results from preclinical studies or clinical trials of our product candidates, including those that are subject to existing or future license or collaboration agreements, are unfavorable, we could be delayed or precluded from the further development or commercialization of our product candidates, which could materially harm our business.***

In order to further advance the development of, and ultimately receive marketing approval to sell our product candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate their safety and efficacy to the satisfaction of the FDA or similar regulatory authorities in other countries, as the case may be. Preclinical studies and clinical trials are expensive, complex, can take many years to complete, and have highly uncertain outcomes. Delays, setbacks, or failures can and do occur at any time, and in any phase of preclinical or clinical testing, and can result from concerns about safety, tolerability, toxicity, a lack of demonstrated biologic activity or improved efficacy over similar products that have been approved for sale or are in more advanced stages of development, poor study or trial design, and issues related to the formulation or manufacturing process of the materials used to conduct the trials. The results of prior preclinical studies or early-stage clinical trials are not predictive of the results we may observe in late-stage clinical trials. In many cases, product candidates in clinical development may fail to show the desired tolerability, safety and efficacy characteristics, despite having favorably demonstrated such characteristics in preclinical studies or early-stage clinical trials.

In addition, we may experience numerous unforeseen events during, or as a result of, preclinical studies and the clinical trial process, which could delay or impede our ability to advance the development of, receive marketing approval for, or commercialize our product candidates, including, but not limited to:

- communications with the FDA, or similar regulatory authorities in different countries, regarding the scope or design of a trial or trials, or placing the development of a product candidate on clinical hold or delaying the next phase of development until questions or issues are satisfactorily resolved, including performing additional studies to answer their queries;
- regulatory authorities or institutional review boards, or IRBs, not authorizing us to commence or conduct a clinical trial at a prospective trial site;
- enrollment in our clinical trials being delayed, or proceeding at a slower pace than we expected, because we have difficulty recruiting participants or participants drop out of our clinical trials at a higher rate than we anticipated;
- our third-party contractors, upon whom we rely to conduct preclinical studies, clinical trials and the manufacturing of our clinical trial materials, failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- having to suspend or ultimately terminate a clinical trial if participants are being exposed to unacceptable health or safety risks;
- regulatory authorities or IRBs requiring that we hold, suspend or terminate our preclinical studies and clinical trials for various reasons, including non-compliance with regulatory requirements; and
- the supply or quality of material necessary to conduct our preclinical studies or clinical trials being insufficient, inadequate or unavailable.

Even if the data collected from preclinical studies or clinical trials involving our product candidates demonstrate a satisfactory tolerability, safety and efficacy profile, such results may not be sufficient to support the submission of a BLA or NDA to obtain regulatory approval from the FDA in the United States, or other similar regulatory authorities in other foreign jurisdictions, which is required for us to market and sell our product candidates.

***We intend to manufacture the vaccine tablets for the upcoming clinical studies for the foreseeable future at our own facility. If we are unable to do so, or we are delayed, or if the cost of manufacturing is not economically feasible or if we cannot find a third-party supplier, we may be unable to produce tablet vaccine candidates in a sufficient quantity to meet future demand.***

From 2012 through the end of December 2017, we relied on a third-party contract manufacturer, Lonza Houston, Inc., for the manufacture, labeling, packaging, storage, and distribution of vaccine tablets to supply the clinical Phase 1 and Phase 2 trials we have conducted to date. We have developed and continue to develop manufacturing processes under cGMP, which we are currently using to manufacture bulk product and vaccine tablets, for future Phase 1 and Phase 2 clinical trials, at our own facility in South San Francisco, California. This transition has resulted in unanticipated delays and lower yields, may result in further unanticipated delays or lower yields or both and may cost more than expected due to a number of factors, including regulatory requirements.If we are unable to manufacture sufficient quantities of our tablet vaccine candidates in a timely manner, our development activities would be impaired and we may need to partner with a third-party supplier.

Our manufacturing facility and equipment is sized to support manufacturing of cGMP product for our Phase 1 and Phase 2a trials, but is not adequate to support larger Phase 2b and Phase 3 trials. Accordingly, we intend to explore opportunities to establish a long-term relationship with an established CMO to develop large scale bulk vaccine production capabilities adequate to support larger trials and commercial product launch. We may be unable to enter into a third-party supplier agreement that is economically feasible or without significant delay.

Our manufacturing facility is subject to ongoing, periodic inspection by the FDA or other comparable regulatory agencies to ensure compliance with cGMP. Any failure to follow and document our adherence to such cGMP regulations or other regulatory requirements may lead to significant delays in the availability of clinical bulk drug substance and finished vaccine tablets for clinical trials, which may result in the termination of, or a hold on, a clinical trial, and may delay or prevent filing or approval of marketing applications for our tablet vaccine candidates. We also may encounter problems with the following:

- achieving adequate or clinical-grade materials that meet FDA or other comparable regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- shortages of qualified personnel, raw materials or key contractors; and
- ongoing compliance with cGMP regulations and other requirements of the FDA or other comparable regulatory agencies.

If we encounter any of these problems or are otherwise delayed, or if the cost of manufacturing at our South San Francisco facility is not economically feasible and we cannot find a third-party contract manufacturer, we may not be able to produce our tablet vaccine candidates in a sufficient quantity to conduct our planned clinical trials and commercialize our vaccine tablet candidates, if approved.

***In the event that we need to engage or subsequently change a third-party contract manufacturer, our preclinical studies or our clinical trials and the commercialization of our product candidates could be delayed, adversely affected or terminated, or such a change may result in the need for us to incur significantly higher costs, which could materially harm our business.***

Due to various regulatory restrictions in the United States and many other countries, as well as potential capacity constraints on manufacturing that occur from time-to-time in our industry, various steps in the manufacture of our product candidates are sole-sourced to certain contract manufacturers. In accordance with cGMPs, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Engaging a third-party contract manufacturer or changing a future contract manufacturer may be difficult and could be extremely costly and time consuming, which could result in our inability to manufacture our product candidates for an extended period of time and a delay in the development of our product candidates. Further, in order to maintain our development timelines in the event of a change in a third-party contract manufacturer, we may incur significantly higher costs to manufacture our product candidates.

***If third-party vendors, upon whom we rely to conduct our preclinical studies or clinical trials, do not perform or fail to comply with strict regulations, these studies or trials may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business.***

We have limited resources dedicated to designing, conducting and managing our preclinical studies and clinical trials. We have historically relied on, and intend to continue to rely on, third parties, including clinical research organizations, consultants and principal investigators, to assist us in designing, managing, conducting, monitoring and analyzing the data from our preclinical studies and clinical trials. We rely on these vendors and individuals to perform many facets of the clinical development process on our behalf, including conducting preclinical studies, the recruitment of sites and patients for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring that these sites are conducting our trials in compliance with the trial protocol and applicable regulations. If these third parties fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the preclinical studies and clinical trials of our product candidates may be delayed or prove unsuccessful.

Further, the FDA, or similar regulatory authorities in other countries, may inspect some of the clinical sites participating in our clinical trials or our third-party vendors' sites to determine if our clinical trials are being conducted according to GCP or similar regulations. If we, or a regulatory authority, determine that our third-party vendors are not in compliance with, or have not conducted our clinical trials according to, applicable regulations, we may be forced to exclude certain data from the results of the trial, or delay, repeat or terminate such clinical trials.

***We have a limited capacity for managing clinical trials, which could delay or impair our ability to initiate or complete clinical trials of our product candidates on a timely basis and materially harm our business.***

We have a limited capacity to recruit and manage all of the clinical trials necessary to obtain approval for our product candidates by the FDA or similar regulatory authorities in other countries. By contrast, larger pharmaceutical and biopharmaceutical companies often have substantial staff or departments with extensive experience in conducting clinical trials with multiple product candidates across multiple indications and obtaining regulatory approval in various countries. In addition, these companies may have greater financial resources to compete for the same clinical investigators, sites and patients that we are attempting to recruit for our clinical trials. As a result, we may be at a competitive disadvantage that could delay the initiation, recruitment, timing and completion of our clinical trials and obtaining of marketing approvals, if achieved at all, for our product candidates.

***Our industry is highly competitive and subject to rapid technological changes. As a result, we may be unable to compete successfully or develop innovative or differentiated products, which could harm our business.***

Our industry is highly competitive and characterized by rapid technological change. Key competitive factors in our industry include, among others, the ability to successfully advance the development of a product candidate through preclinical and clinical trials; the efficacy, toxicology, tolerability, safety, resistance or cross-resistance, interaction or dosing profile of a product or product candidate; the timing and scope of marketing approvals, if ever achieved; reimbursement rates for and the average selling price of competing products and pharmaceutical products in general; the availability of raw materials and qualified contract manufacturing and manufacturing capacity to produce our product candidates; relative manufacturing costs; establishing, maintaining and protecting our intellectual property and patent rights; and sales and marketing capabilities.

Developing pharmaceutical product candidates is a highly competitive, expensive and risky activity with a long business cycle. Many organizations, including the large pharmaceutical and biopharmaceutical companies that have existing products on the market or in clinical development that may compete with our product candidates, have substantially more resources than us, as well as much greater capabilities and experience than we have in research and discovery, designing and conducting preclinical studies and clinical trials, operating in a highly regulated environment, formulating and manufacturing drug substances, products and devices, and marketing and sales. Our competitors may be more successful than us in obtaining regulatory approvals for their product candidates and achieving broad market acceptance once they are approved. Our competitors' products or product candidates may be more effective, have fewer adverse effects, be more convenient to administer, have a more favorable resistance profile, or be more effectively marketed and sold than any product that we, or our potential future licensees or collaborators, may develop or commercialize. New drugs or classes of drugs from competitors may render our product candidates obsolete or non-competitive before we are able to successfully develop them or, if approved, before we can recover the expenses of developing and commercializing them. We anticipate that we, or our potential future licensees or collaborators, will face intense and increasing competition as new drugs and drug classes enter the market and advanced technologies or new drug targets become available. If our product candidates do not demonstrate any meaningful competitive advantages over existing products, or new products or product candidates, we may terminate the development or commercialization of our product candidates at any time.

Our competitors, either alone or with their collaborators, may succeed in developing product candidates or products that are more effective, safer, less expensive or easier to administer than ours. Accordingly, our competitors may succeed in obtaining regulatory approval for their product candidates more rapidly than we can. Companies that can complete clinical trials, obtain required marketing approvals and commercialize their products before their competitors do so may achieve a significant competitive advantage, including certain patent and marketing exclusivity rights that could delay the ability of competitors to market certain products.

We also face, and expect that we will continue to face, intense competition from other companies in a number of other areas, including (i) attracting larger pharmaceutical and biopharmaceutical companies to enter into collaborative arrangements with us to acquire, license or co-develop our product candidates, (ii) identifying and obtaining additional clinical-stage development programs to bolster our pipeline, (iii) attracting investigators and clinical sites capable of conducting our clinical trials, and (iv) recruiting patients to participate in our clinical trials. There can be no assurance that product candidates resulting from our research and development efforts, or from joint efforts with our potential future licensees or collaborators, will be able to compete successfully with our competitors' existing products or product candidates in development.

***We may be unable to successfully develop a product candidate that is the subject of an existing or future license agreement or collaboration if our licensee or collaborator does not perform or fulfill its contractual obligations, delays the development of our product candidate, or terminates the agreement.***

We expect to continue to enter into and rely on license and collaboration agreements in the future, or other similar business arrangements with third parties, to further develop and/or commercialize some or all of our existing and future product candidates. Such licensees or collaborators may not perform as agreed upon or anticipated, may fail to comply with strict regulations, or may elect to delay or terminate their efforts in developing or commercializing our product candidates even though we have met our obligations under the arrangement.

A majority of the potential revenue from existing and any future licenses and collaborations we may enter into will likely consist of contingent milestone payments, such as payments received for achieving development or regulatory milestones, and royalties payable on the sales of approved products. Milestone and royalty revenues that we may receive under these licenses and collaborations will depend primarily upon our licensees' or collaborators' ability to successfully develop and commercialize our product candidates. In addition, our licensees or collaborators may decide to enter into arrangements with third parties to commercialize products developed under our existing or future collaborations using our technologies, which could reduce the milestone and royalty revenue that we may receive, if any. In many cases, we will not be directly or closely involved in the development or commercialization of our product candidates that are subject to licenses or collaborations and, accordingly, we will depend largely on our licensees or collaborators to develop or commercialize our product candidates. Our licensees may encounter competition from new products entering the market, which could adversely affect our royalty income. Our licensees or collaborators may fail to develop or effectively commercialize our product candidates because they:

- do not allocate the necessary resources due to internal constraints, such as limited personnel with the requisite scientific expertise, limited capital resources, or the belief that other product candidates or internal programs may have a higher likelihood of obtaining regulatory approval, or may potentially generate a greater return on investment;
- do not have sufficient resources necessary to fully support the product candidate through clinical development, regulatory approval and commercialization;
- are unable to obtain the necessary regulatory approvals; or
- prioritize other programs or otherwise diminish their support for developing and/or marketing our product candidate or product due to a change in management, business operations or strategy.

Should any of these events occur, we may not realize the full potential or intended benefit of our license or collaboration arrangements, and our results of operations may be adversely affected. In addition, a licensee or collaborator may decide to pursue the development of a competitive product candidate developed outside of our agreement with them. Conflicts may also arise if there is a dispute about the progress of, or other activities related to, the clinical development or commercialization of a product candidate, the achievement and payment of a milestone amount, the ownership of intellectual property that is developed during the course of the arrangement, or other license agreement terms. If a licensee or collaborator fails to develop or effectively commercialize our product candidates for any of these reasons, we may not be able to replace them with another third party willing to develop and commercialize our product candidates under similar terms, if at all. Similarly, we may disagree with a licensee or collaborator as to which party owns newly or jointly-developed intellectual property. Should an agreement be revised or terminated as a result of a dispute and before we have realized the anticipated benefits of the arrangement, we may not be able to obtain certain development support or revenues that we anticipated receiving. We may also be unable to obtain, on terms acceptable to us, a license from such collaboration partner to any of its intellectual property that may be necessary or useful for us to continue to develop and commercialize the product candidate. There can be no assurance that any product candidates will emerge from any existing or future license or collaboration agreements we may enter into for any of our product candidates.

***If government and third-party payers fail to provide adequate reimbursement or coverage for our products or those that are developed through licenses or collaborations, our revenues and potential for profitability may be harmed.***

In the United States and most foreign markets, product revenues or related royalty revenue, and therefore the inherent value of our products, will depend largely upon the reimbursement rates established by third-party payers for such products. Third-party payers include government health administration authorities, managed-care organizations, private health insurers and other similar organizations. Third-party payers are increasingly examining the cost effectiveness of medical products, services and pharmaceutical drugs and challenging the price of these products and services. In addition, significant uncertainty exists as to the reimbursement status, if any, of newly approved pharmaceutical products. Further, the comparative effectiveness of new products over existing therapies and the assessment of other non-clinical outcomes are increasingly being considered in the decision by payers to establish reimbursement rates. We, or our licensees or collaborators if applicable, may also be required to conduct post-marketing clinical trials in order to demonstrate the cost-effectiveness of our products. Such studies may require us to commit a significant amount of management time and financial resources. There can be no assurance that any products that we or our licensees or collaborators may successfully develop will be reimbursed in part, or at all, by any third-party payers in any country.

Many governments continue to propose legislation designed to expand the coverage, yet reduce the cost, of healthcare, including pharmaceutical products. In many foreign markets, governmental agencies control the pricing of prescription drugs. In the United States, significant changes in federal health care policy were approved over the past several years and continue to evolve and will likely result in reduced reimbursement rates for many pharmaceutical products in the future. We expect that there will continue to be federal and state proposals to implement increased government control over reimbursement rates of pharmaceutical products. In addition, we expect that increasing emphasis on managed care and government intervention in the U.S. healthcare system will continue to put downward pressure on the pricing of pharmaceutical products there. Recent events have resulted in increased public and governmental scrutiny of the cost of drugs, especially in connection with price increases following companies' acquisitions of the rights to certain drug products. In particular, U.S. federal prosecutors recently issued subpoenas to a pharmaceutical company seeking information about its drug pricing practices, among other issues, and members of the U.S. Congress have sought information from certain pharmaceutical companies relating to post-acquisition drug-price increases. Our revenue and future profitability could be negatively affected if these inquiries were to result in legislative or regulatory proposals that limit our ability to increase the prices of our products that may be approved for sale in the future. Legislation and regulations affecting the pricing of pharmaceutical products may change before our product candidates are approved for sale, which could further limit or eliminate their reimbursement rates. Further, social and patient activist groups, whose goal it is to reduce the cost of healthcare, and in particular the price of pharmaceutical products, may also place downward pressure on the price of these products, which could result in decreases in the price of our products.

***If any product candidates that we develop independently, or through licensees or collaborators if applicable, are approved but do not gain meaningful acceptance in their intended markets, we are not likely to generate significant revenues.***

Even if our product candidates are successfully developed and we or a licensee or collaborator obtains the requisite regulatory approvals to market them in the future, they may not gain market acceptance or broad utilization among physicians, patients or third-party payers. The degree of market acceptance that any of our products may achieve will depend on a number of factors, including:

- the efficacy or perceived clinical benefit of the product, if any, relative to existing therapies;
- the timing of market approval and the existing market for competitive drugs, including the presence of generic drugs;
- the level of reimbursement provided by third-party payers to cover the cost of the product to patients;
- the net cost of the product to the user or third-party payer;
- the convenience and ease of administration of the product;
- the product's potential advantages over existing or alternative therapies;
- the actual or perceived safety of similar classes of products;
- the actual or perceived existence, incidence and severity of adverse effects;
- the effectiveness of sales, marketing and distribution capabilities; and
- the scope of the product label approved by the FDA or similar regulatory agencies in other jurisdictions.

There can be no assurance that physicians will choose to prescribe or administer our products, if approved, to the intended patient population. If our products do not achieve meaningful market acceptance, or if the market for our products proves to be smaller than anticipated, we may never generate significant revenues.

***Our headquarters is located near known earthquake fault zones. The occurrence of an earthquake, fire or any other catastrophic event could disrupt our operations or the operations of third parties who provide vital support functions to us, which could have a material adverse effect on our business and financial condition.***

We are vulnerable to damage from catastrophic events, such as power loss, natural disasters, terrorism and similar unforeseen events beyond our control. Our corporate headquarters and other facilities are located in the San Francisco Bay Area, which in the past has experienced severe earthquakes and fires.

We do not have a disaster recovery and business continuity plan in place. Earthquakes or other natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as our financial systems or manufacturing facility, or that otherwise disrupted our operations, it may be difficult or, in certain cases, impossible for us to continue business operations for a substantial period of time.

***Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including most recently on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

**Risks Related to Dependence on Third Parties**

***If third-party contract manufacturers, upon whom we may have to rely to formulate and manufacture our product candidates, do not perform, fail to manufacture according to our specifications, or fail to comply with strict government regulations, our preclinical studies or clinical trials could be adversely affected and the development of our product candidates could be delayed or terminated, or we could incur significant additional expenses.***

In the event that we place reliance on third-party contract manufacturers, which in some cases may be sole sourced, we would be exposed to a number of risks, any of which could delay or prevent the completion of our preclinical studies or clinical trials, or the regulatory approval or commercialization of our product candidates, result in higher costs, or deprive us of potential product revenues in the future. Some of these risks include, but are not limited to:

- our potential contract manufacturers failing to develop an acceptable formulation to support late-stage clinical trials for, or the commercialization of, our product candidates;
- our potential contract manufacturers failing to manufacture our product candidates according to their own standards, our specifications, current good manufacturing practices, or cGMP, or regulatory guidelines, or otherwise manufacturing material that we or regulatory authorities deem to be unsuitable for our clinical trials or commercial use;
- our potential contract manufacturers being unable to increase the scale of or the capacity for, or reformulate the form of, our product candidates, which may cause us to experience a shortage in supply or cause the cost to manufacture our product candidates to increase. There can be no assurance that our potential contract manufacturers will be able to manufacture our product candidates at a suitable commercial scale, or that we will be able to find alternative manufacturers acceptable to us that can do so;
- our potential contract manufacturers placing a priority on the manufacture of other customers' or their own products, rather than our products;
- our potential contract manufacturers failing to perform as agreed or exiting from the contract manufacturing business; and
- our potential contract manufacturers' plants being closed as a result of regulatory sanctions or a natural disaster.

Manufacturers of pharmaceutical drug products are subject to ongoing periodic inspections by the FDA, the U.S. Drug Enforcement Administration, or DEA, and corresponding state and other foreign agencies to ensure strict compliance with FDA-mandated cGMPs, other government regulations and corresponding foreign standards. We do not have control over our third-party contract manufacturers' compliance with these regulations and standards and accordingly, failure by our third-party manufacturers, or us, to comply with applicable regulations could result in sanctions being imposed on us or our manufacturers, which could significantly and adversely affect our business.

***In the event that we need to engage or subsequently change a third-party contract manufacturer, our preclinical studies or our clinical trials, and the commercialization of our product candidates could be delayed, adversely affected or terminated, or such a change may result in the need for us to incur significantly higher costs, which could materially harm our business.***

Due to various regulatory restrictions in the United States and many other countries, as well as potential capacity constraints on manufacturing that occur from time-to-time in our industry, various steps in the manufacture of our product candidates are sole-sourced to certain contract manufacturers. In accordance with cGMPs, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Engaging a third-party contract manufacturer or changing a future contract manufacturer may be difficult and could be extremely costly and time-consuming, which could result in our inability to manufacture our product candidates for an extended period of time and a delay, as well as an increase in costs, in the development of our product candidates.

***We may not be able to manufacture our product candidates in sufficient quantities to commercialize them.***

In order to receive FDA approval of our product candidates, we will need to manufacture such product candidates in larger quantities. We may not be able to increase successfully the manufacturing capacity for our product candidates in a timely or economic manner, or at all. In the event FDA approval is received, we will need to increase production of our product candidates. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for our product candidates, the clinical trials, the regulatory approval and the commercial launch of our product candidates may be delayed, or there may be a shortage in supply. Our product candidates require precise, high-quality manufacturing. Failure to achieve and maintain high-quality manufacturing, including the incidence of manufacturing errors, could result in patient injury or death, delays or failures in testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations.

***The manufacture of pharmaceutical products in compliance with cGMP regulations requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls.***

Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including stability of the product candidates and quality assurance testing, or shortages of qualified personnel. If we were to encounter any of these difficulties or otherwise fail to comply with our obligations under applicable regulations, our ability to provide study materials in our clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial materials could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial programs and, depending upon the period of delay, require us to commence new trials at significant additional expense or to terminate the studies and trials completely.

We must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our component materials may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies at any time may also implement new standards, or change their interpretation and enforcement of existing standards, for manufacture, packaging or testing of products. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any product supplied is compromised due to our failure, or that our third-party manufacturers, to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of any product candidates we may develop or acquire in the future, or entail higher costs, or impair our reputation.

***We currently rely on single source vendors for key tablet vaccine components and certain strains needed in our tablet vaccine candidates, which could impair our ability to manufacture and supply our tablet vaccine candidates.***

We currently depend on single source vendors for certain raw materials used in the manufacture of our tablet vaccine candidates. Any production shortfall that impairs the supply of the relevant raw materials could have a material adverse effect on our business, financial condition and results of operations. An inability to continue to source product from these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could materially adversely affect our operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

***We intend to rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.***

We intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance.

We intend to rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of these regulatory responsibilities.

We and our CROs will be required to comply with the Good Laboratory Practices and GCPs, which are regulations and guidelines enforced by the FDA and are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate significant revenues could be delayed.

If our relationship with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

***We may seek to selectively establish collaborations, and, if we are unable to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.***

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, including our seasonable influenza and RSV tablets, we may decide to collaborate with governmental entities or additional pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

***Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal FCA imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring vaccine manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

**Risks Related to Intellectual Property**

***If we are unable to obtain and maintain patent protection for our oral vaccine platform technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.***

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain and enforce any patents that may issue from such patent applications, at a reasonable cost or in a timely manner.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own may fail to result in issued patents with claims that cover any of our product candidates in the United States or in other countries. There is no assurance that the entire potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates or companion diagnostic that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate and companion diagnostic under patent protection could be reduced.

If the patent applications we hold with respect to our platform technology and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize future drugs. Any such outcome could harm our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and vaccines. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative product candidates in a non-infringing manner. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. In other countries, we may be subject to or become involved in opposition proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission or proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and tablet vaccines, or limit the duration of the patent protection of our technology and product candidates. Moreover, patents have a limited lifespan. In the United States and other countries, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available, however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current or future tablet vaccine candidates, we may be open to competition from generic versions of such product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

***If we are unable to adequately protect or expand our intellectual property related to products acquired in the Merger, our business prospects could be harmed.***

We can protect our proprietary intellectual property rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of pharmaceutical and biopharmaceutical companies involves complex legal and factual questions, and, therefore, we cannot predict with certainty whether we will be able to ultimately enforce our patents or proprietary rights or avoid infringing on the patents or proprietary rights of others. Any issued patents that we own or otherwise have rights to may be challenged, invalidated or circumvented, and may not provide us with the protection against competitors that we anticipate.

The degree of future protection of our proprietary intellectual property rights is uncertain because issued patents and other legal means of establishing proprietary rights afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Our future patent position will be influenced by the following factors:

- we, or our licensors, may not have been the first to discover the inventions covered by each of our, or our licensors', pending patent applications and issued patents, and we may have to engage in expensive and protracted interference proceedings to determine priority of invention;
- our, or our licensors', pending patent applications may be denied and may not result in issued patents;
- our, or our licensors', issued patents may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be challenged by third parties; and
- third parties may develop intellectual property that circumvents our, or our licensors', patent claims, or design competitive intellectual property and ultimately product candidates that fall outside the scope of our, or our licensors', patents.

Due to the extensive time required for the development, testing and regulatory review and approval of a product candidate, it is possible that before our product candidates may be approved for sale and commercialized, our relevant patent rights may expire, or such patent rights may remain in force for only a short period following marketing approval. We currently rely on certain patents to provide us and our licensees with exclusive rights for certain of our products. When all patents underlying a license expire, our revenue from that license may cease, and there can be no assurance that we will be able to replace it with revenue from new or existing licenses.

Zanamivir, a neuraminidase inhibitor ("NI") approved for the treatment and prevention of influenza A and B, is marketed worldwide as Relenza by GSK. Most of our Relenza patents have expired and the only substantial remaining intellectual property related to the Relenza patent portfolio, which we own and have exclusively licensed to GSK, is scheduled to expire in July 2019 in Japan.

Patent rights may not provide us with adequate proprietary protection or competitive advantages against competitors with or developing similar technologies or approaches to ours. The laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States, and certain countries may lack adequate rules and procedures for defending our intellectual property rights. For example, we may not be able to prevent a third-party from infringing our patents in a country that does not recognize or enforce patent rights, or that imposes compulsory licenses on, or restricts the prices of, drugs. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We may need to in-license certain technologies to successfully develop and commercialize our product candidates. We may not develop or obtain rights to products or processes that are patentable. Even if we, or our licensors, do obtain patents, such patents may not adequately protect the products or technologies licensed, or may otherwise be limited in scope. In addition, we may not have total control over the patent prosecution of subject matter that we license from others. Accordingly, we may be unable to exercise the same degree of control over this intellectual property as we would over our own. Others may challenge, seek to invalidate, infringe or circumvent any pending or issued patents we own or license, and rights we receive under those issued patents may not provide us with competitive advantages. There can be no assurance of the degree of protection that will be afforded by any of our issued or pending patents, or those we license.

There can be no assurance that any patents will be issued from the patent applications we own or have licensed or, should any patents be issued, that we will be provided with adequate protection against potentially competitive products. Furthermore, we cannot be sure that patents issued or licensed to us will be of any commercial value, or that private parties or competitors will not successfully challenge these patents or circumvent our patent position in the United States or abroad. In the absence of adequate patent protection, our business may be adversely affected by competitors who develop comparable technology or products.

***We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that such patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third-party may also cause the third-party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third-party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

***If a third party claims we are infringing on its intellectual property rights, we could incur significant expenses, or be prevented from further developing or commercializing our product candidates, which could materially harm our business.***

Our success will largely depend on our ability to operate without infringing the patents and other proprietary intellectual property rights of third parties. This is generally referred to as having the "freedom to operate." However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current or future product candidates may be subject to claims of infringement of the patent rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. The defense and prosecution of intellectual property claims, interference proceedings and related legal and administrative proceedings, both in the United States and internationally, involve complex legal and factual questions. As a result, such proceedings are lengthy, costly and time-consuming, and their outcome is highly uncertain. We may become involved in protracted and expensive litigation in order to determine the enforceability, scope and validity of the proprietary rights of others, or to determine whether we have the freedom to operate with respect to the intellectual property rights of others.

Patent applications in the United States are, in most cases, maintained in secrecy until approximately 18 months after the patent application is filed. The publication of discoveries in scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patent applications relating to product candidates similar to ours may have already been filed by others without our knowledge. In the event that a third party has also filed a patent application covering our product candidate or other claims, we may have to participate in an adversarial proceeding, known as an interference proceeding, in the USPTO, or similar proceedings in other countries, to determine the priority of invention. In the event an infringement claim is brought against us, we may be required to pay substantial legal fees and other expenses to defend such a claim and, should we be unsuccessful in defending the claim, we may be prevented from pursuing the development and commercialization of a product candidate and may be subject to injunctions and/or damage awards.

In the future, the USPTO or a foreign patent office may grant patent rights to our product candidates or other claims to third parties. Subject to the issuance of these future patents, the claims of which will be unknown until issued, we may need to obtain a license or sublicense to these rights in order to have the appropriate freedom to further develop or commercialize them. Any required licenses may not be available to us on acceptable terms, if at all. If we need to obtain such licenses or sublicenses, but are unable to do so, we could encounter delays in the development of our product candidates, or be prevented from developing, manufacturing and commercializing our product candidates at all. If it is determined that we have infringed an issued patent and do not have the freedom to operate, we could be subject to injunctions, and/or compelled to pay significant damages, including punitive damages. In cases where we have in-licensed intellectual property, our failure to comply with the terms and conditions of such agreements could harm our business.

It is becoming common for third parties to challenge patent claims on any successfully developed product candidate or approved drug. If we or our licensees or collaborators become involved in any patent litigation, interference or other legal proceedings, we could incur substantial expense, and the efforts and attention of our technical and management personnel could be significantly diverted. A negative outcome of such litigation or proceedings may expose us to the loss of our proprietary position or to significant liabilities or require us to seek licenses that may not be available from third parties on commercially acceptable terms, if at all. We may be restricted or prevented from developing, manufacturing and selling our product candidates in the event of an adverse determination in a judicial or administrative proceeding, or if we fail to obtain necessary licenses.

***Obtaining and maintaining our patent protection depends on compliance with various procedures, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedures, documentary fee payments and other provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we and our licensors fail to maintain the patents and patent applications covering our product candidates, our competitive position would be adversely affected.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

The United States has recently enacted and implemented wide-ranging patent reform legislation. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future.

***We may not be able to protect our intellectual property rights throughout the world, which could impair our business.***

Filing, prosecuting and defending patents covering our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own vaccines and, further, may export otherwise infringing vaccines to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These vaccines may compete with our product candidates in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

Many of our employees, including our senior management, were previously employed at universities or other biotechnology or pharmaceutical companies. These employees typically executed proprietary rights, non-disclosure and non-competition agreements in connection with their previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that it or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

***Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.***

We seek to protect our proprietary technology in part by entering into confidentiality agreements with third parties and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development, or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

***Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.***

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive vaccines and medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be materially harmed.

***We may be subject to claims challenging the inventorship of our patents and other intellectual property.***

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

## Item 1B. Unresolved Staff Comments

None.

## Item 2. Properties

We do not own any real property. Our leased facilities as of December 31, 2018, are as follows:

| Location | Square Feet | Primary Use | Lease Terms |
|---|---|---|---|
| South San Francisco, CA | 22,427 sq ft | Laboratory and office | Four leases expiring between August 2019 and April 2020 |
| Alpharetta, GA | 11,788 sq ft | Office | Lease expires February 2021; entire office subleased |

We believe that our existing facilities are adequate for our current needs. We plan to consolidate our facilities in South San Francisco in 2019 and believe that sufficient options are available to us on commercially reasonable terms.

## Item 3. Legal Proceedings

From time to time we may be involved in claims arising in connection with our business. Based on information currently available, we believe that the amount, or range, of reasonably possible losses in connection with any pending actions against us, in excess of established reserves, in the aggregate, not to be material to our consolidated financial condition or cash flows. However, losses may be material to the Company's operating results for any particular future period, depending on the level of income for such period.

## Item 4. Mine Safety Disclosures

Not applicable.

# PART II

## Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

### Trading Information

Since February 14, 2018, our common stock has traded on the Nasdaq Capital Market under the symbol "VXRT". Prior to that, since April 13, 2016, our common stock traded under the symbol "AVIR", prior to which it had traded under the symbol "BOTA" since November 8, 2012, prior to which it had traded under the symbol "NABI". The transfer agent for our common stock is American Stock Transfer & Trust Company, LLC at 6201 15 th Avenue, Brooklyn, NY 11219. All of our electronic filings are available on the SEC's website at www.sec.gov. We maintain our own website on the internet at www.vaxart.com.

As of January 31, 2019, there were approximately 6,608 holders of record of our common stock.

### Dividend Policy

We have never declared or paid dividends on shares of our common stock. We intend to retain future earnings, if any, to support the development of our business and therefore do not anticipate paying cash dividends for the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including current financial condition, operating results and current and anticipated cash needs. Our ability to declare and pay dividends on shares of our common stock is restricted by our credit facility with Oxford Finance, LLC.

## Item 6. Selected Financial Data

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information under this item.

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the other sections of this Annual Report on Form 10-K, including our consolidated financial statements and notes thereto included elsewhere. This discussion contains a number of forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in the Annual Report on Form 10-K, particularly in Item 1A – "Risk Factors." The forward-looking statements made in this Annual Report on Form 10-K are made only as of the date hereof.*

**Company Overview**

We are a clinical-stage biotechnology company focused on the development of oral recombinant vaccines based on our proprietary oral vaccine platform. Our oral vaccines are designed to generate broad and durable immune responses that protect against a wide range of infectious diseases and may be useful for the treatment of chronic viral infections and cancer. Our vaccines are administered using a convenient room temperature-stable tablet, rather than by injection.

We are developing prophylactic vaccine candidates that target a range of infectious diseases. These include norovirus, a widespread cause of acute gastro-intestinal enteritis, for which two Phase 1 human studies have been completed; seasonal influenza, for which our vaccine protected patients in a recent Phase 2 challenge study; and respiratory syncytial virus, or RSV, a common cause of respiratory tract infections. In addition, we are developing our first therapeutic immune-oncology vaccine targeting cervical cancer and dysplasia caused by human papillomavirus, or HPV.

Through our merger with Aviragen Therapeutics, Inc., or Aviragen, we acquired three Phase 2 clinical stage antiviral compounds, which we are no longer actively pursuing: (1) BTA074, or teslexivir, an antiviral treatment for condyloma caused by human papillomavirus types 6 & 11; (2) vapendavir, a capsid inhibitor for the prevention or treatment of rhinovirus upper respiratory infections; and (3) BTA585, or enzaplatovir, a fusion protein inhibitor for the treatment of RSV infections. We have discontinued all three programs.

**Merger with Aviragen**

Vaxart Biosciences, Inc. was originally incorporated in California in March 2004, under the name West Coast Biologicals, Inc. and changed its name to Vaxart, Inc., or Private Vaxart, in July 2007, and reincorporated in the state of Delaware.

On February 13, 2018, Private Vaxart completed a reverse merger, or the Merger, with Aviragen, pursuant to which Private Vaxart survived as a wholly owned subsidiary of Aviragen. Under the terms of the Merger, Aviragen changed its name to Vaxart, Inc. and Private Vaxart changed its name to Vaxart Biosciences, Inc. Immediately prior to the Merger, all of Private Vaxart's convertible promissory notes and convertible preferred stock were converted into common stock, following which each share of common stock was converted into approximately 0.22148 shares of common stock.

Immediately following the completion of the Merger, we effected a reverse stock split at a ratio of one new share for every eleven shares of our common stock outstanding, or the Reverse Stock Split.All share, equity security and per share amounts are presented to give retroactive effect to the Reverse Stock Split. Immediately after the Merger and the Reverse Stock Split there were approximately 7.1 million shares of common stock outstanding. In addition, immediately after the Merger, Private Vaxart's stockholders, warrantholders and optionholders owned approximately 51% of the common stock of the combined company and the stockholders and optionholders of Aviragen immediately prior to the Merger owned approximately 49% of the common stock of the combined company (on a fully diluted basis).

**Financial Operations Overview**

***Revenue***

*Revenue from Government Contract*

The government contract with HHS BARDA, as modified, was a cost-plus-fixed-fee contract, under which we were reimbursed for allowable direct contract costs plus allowable indirect costs and a fixed-fee totaling $15.7 million from September 2015 through September 30, 2018. Activities were completed in 2018 and no future revenue is expected from this contract.

*Royalty Revenue*

We earn royalty revenue on sales of Relenza and Inavir both treatments for influenza, by our licensees GlaxoSmithKline, plc and Daiichi Sankyo Company, Limited, respectively, based on fixed percentages of net sales of these drugs.

*Non-Cash Royalty Revenue Related to the Sale of Future Royalties*

In April 2016, Aviragen sold certain royalty rights related to Inavir in the Japanese market for $20.0 million to HealthCare Royalty Partners III, L.P., or HCRP. At the time of the Merger, the estimated future benefit to HCRP was remeasured at fair value and was estimated to be $15.9 million, which we account for as a liability and amortize using the effective interest method over the remaining estimated life of the arrangement. Even though we did not retain the related royalties under the transaction, as the amounts are remitted to HCRP, we will continue to record revenue related to these royalties until the amount of the associated liability and related interest is fully amortized.

***Research and Development Expenses***

Research and development expenses represent costs incurred to conduct research, including the development of our tablet vaccine platform, and the manufacturing, preclinical and clinical development activities of our tablet vaccine candidates. We recognize all research and development costs as they are incurred. Research and development expenses consist primarily of the following:

- employee-related expenses, which include salaries, benefits and stock-based compensation;
- expenses incurred under agreements with contract research organizations, or CROs, that conduct clinical trials on our behalf;
- manufacturing materials, analytical and release testing services required for our production of vaccine candidates used primarily in clinical trials;
- process development expenses incurred internally and externally to improve the efficiency and yield of the bulk vaccine and tablet manufacturing activities;
- laboratory supplies and vendor expenses related to its preclinical research activities;
- consultant expenses for services supporting our clinical, regulatory and manufacturing activities; and
- facilities, depreciation and allocated overhead expenses.

We do not allocate our internal expenses to specific programs. Our employees and other internal resources are not directly tied to any one research program and are typically deployed across multiple projects. Internal research and development expenses are presented as one total.

We incur significant external costs on manufacturing our tablet vaccine candidates, and on CROs that conduct clinical trials on our behalf. We capture these expenses for each vaccine program. We do not allocate external costs incurred on preclinical research or process development to specific programs.

The following table shows our research and development expenses for 2018 and 2017, identifying external costs that were incurred in each of our vaccine programs and, separately, on preclinical research and process development:

| | Year Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| | (in thousands) | |
| External program costs: | | |
| Influenza program, funded by BARDA | $ 749 | $ 4,451 |
| Influenza program, non-BARDA | — | 44 |
| Norovirus program | 2,578 | 1,431 |
| RSV program | 53 | 325 |
| Teslexivir and vapendavir programs | 1,902 | — |
| Preclinical research and process development | 285 | 242 |
| Total external costs | 5,567 | 6,493 |
| Internal costs | 11,708 | 5,862 |
| | $ 17,275 | $ 12,355 |

We expect that our research and development expenses will increase significantly over the next several years as we advance our tablet vaccine candidates into and through clinical trials, pursue regulatory approval of our tablet vaccine candidates and prepare for a possible commercial launch, all of which will also require a significant investment in manufacturing and inventory related costs.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing approval for our tablet vaccine candidates. The probability of successful commercialization of our tablet vaccine candidates may be affected by numerous factors, including clinical data obtained in future trials, competition, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our tablet vaccine candidates.

***General and Administrative Expense***

General and administrative expenses consist of personnel costs, allocated expenses and expenses for outside professional services, including legal, audit, accounting, public relations, market research and other consulting services. Personnel costs consist of salaries, benefits and stock-based compensation. Allocated expenses consist of rent, depreciation and other facilities related expenses. We expect to continue to incur additional expenses as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission, or SEC, the Nasdaq Capital Market as well as additional insurance, investor relations and other professional expenses.

**Results of Operations**

The following table presents selected items in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2018 and 2017, which include the operations of Aviragen for the period from February 13, 2018 to December 31, 2018:

| | Year Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| | (in thousands) | |
| Revenue: | | |
| Revenue from government contract | $ 1,344 | $ 5,839 |
| Royalty revenue | 1,340 | — |
| Non-cash royalty revenue related to the sale of future royalties | 1,475 | — |
| Total revenue | 4,159 | 5,839 |
| Operating expenses: | | |
| Research and development | 17,275 | 12,355 |
| General and administrative | 6,681 | 3,499 |
| Impairment of intangible assets | 1,600 | — |
| Costs of exit from leased premises | 359 | — |
| Total operating expenses | 25,915 | 15,854 |
| Operating loss | (21,756) | (10,015) |
| Other income and (expenses): | | |
| Bargain purchase gain | 6,760 | — |
| Interest income | 58 | 53 |
| Interest expense | (821) | (3,036) |
| Non-cash interest expense related to sale of future royalties | (1,859) | — |
| (Loss) gain on sale of equipment | (11) | 69 |
| (Loss) gain on revaluation of financial instruments, net | (3) | 3,347 |
| Foreign exchange loss | (266) | — |
| Total other income and (expenses) | 3,858 | 433 |
| Net loss before provision for income taxes | (17,898) | (9,582) |
| Provision for income taxes | 109 | — |
| Net loss | $ (18,007) | $ (9,582) |

*Revenue from Government Contract*

The following table presents revenue from our government contract for 2018 and 2017:

| Year Ended December 31, | | |
|---|---|---|
| 2018 | 2017 | % Change |
| (dollars in thousands) | | |
| $ 1,344 | $ 5,839 | (77)% |

For 2018, revenue from our government contract decreased by $4.5 million, or 77%, compared to 2017. The active phase of the contract occurred in 2016 and 2017. In 2018 activities were wound down and completed and no future revenue is expected from this contract.

*Royalty Revenue*

The following table presents our royalty revenue for 2018 and 2017:

| Year Ended December 31, | | |
|---|---|---|
| 2018 | 2017 | % Change |
| (dollars in thousands) | | |
| $ 1,340 | $ — | N/A |

For 2018, royalty revenue was $1.3 million in the post-Merger period. We recorded no such revenue prior to the Merger.

*Non-cash Royalty Revenue Related to the Sale of Future Royalties*

The following table presents our non-cash royalty revenue related to the sale of future royalties for 2018 and 2017:

| Year Ended December 31, | | |
|---|---|---|
| 2018 | 2017 | % Change |
| (dollars in thousands) | | |
| $ 1,475 | $ — | N/A |

For 2018, non-cash royalty revenue related to the sale of future royalties was $1.5 million in the post-Merger period. We recorded no such revenue prior to the Merger.

*Research and Development*

The following table presents our research and development expenses for 2018 and 2017:

| Year Ended December 31, | | |
|---|---|---|
| 2018 | 2017 | % Change |
| (dollars in thousands) | | |
| $ 17,275 | $ 12,355 | 40% |

For 2018, research and development expenses increased by $4.9 million, or 40%, compared to 2017. The increase in 2018 is principally due to amortization of intangible assets acquired in the Merger, clinical trials of teslexivir and vapendavir, higher personnel costs due to an increase in headcount and increased costs for facilities, manufacturing costs and laboratory supplies for tablet vaccine research. These increases were partially offset by lower expenditures incurred under the HHS BARDA contract. We expect that research and development expenses will increase in the near term as we plan to conduct two norovirus clinical trials in 2019, which will only be partially offset by the elimination of expenses that we were formerly incurring under the HHS BARDA contract.

*General and Administrative*

The following table presents our general and administrative expenses for 2018 and 2017:

| Year Ended December 31, | | |
|---|---|---|
| 2018 | 2017 | % Change |
| (dollars in thousands) | | |
| $ 6,681 | $ 3,499 | 91% |

General and administrative expenses consist of personnel costs, allocated overhead expenses and expenses for outside professional services, including legal, audit, accounting, investor relations, market research and other consulting services. Personnel costs consist of salaries, benefits and stock-based compensation. Allocated overhead expenses consist of rent, depreciation and other facilities related expenses.

For 2018, general and administrative expenses increased by $3.2 million, or 91%, compared to 2017. The increase in 2018 is due principally due to an increase in legal and other professional costs and additional expenses incurred as a public company, including expenses related to compliance with the rules and regulations of the SEC and the Nasdaq Capital Market, as well as additional insurance, investor relations and directors' fees. Personnel and related facilities costs also increased due to an increased headcount and the overlap of personnel due to transitioning following the Merger. Approximately $0.5 million and $0.9 million in 2018 and 2017, respectively, were incurred for legal, accounting and other third-party costs related directly to the Merger and are not expected to recur.

*Impairment of Intangible Assets*

The following table presents the impairment of our intangible assets for 2018 and 2017:

| Year Ended December 31, | | |
|---|---|---|
| 2018 | 2017 | % Change |
| (dollars in thousands) | | |
| $ 1,600 | $ — | N/A |

Impairment of intangible assets represents the write-off of the in-process research and development related to teslexivir that we acquired in the Merger. Since the Phase 2 trial completed in May 2018 did not achieve the primary efficacy endpoint and we have suspended development activities, we now consider this asset to be fully impaired.

*Costs of Exit from Leased Premises*

The following table presents the costs of exit from leased premises for 2018 and 2017:

| Year Ended December 31, | | |
|---|---|---|
| 2018 | 2017 | % Change |
| (dollars in thousands) | | |
| $ 359 | $ — | N/A |

Costs of exit from leasehold premises comprise both our lease loss accrual and our write-down of leasehold improvements and furniture at our leased premises in Alpharetta, Georgia. Since this facility had surplus capacity, we subleased these premises, commencing in November 2018, for the remainder of the lease term for less than we are presently paying. Accordingly, we recorded an exit charge consisting of loss on lease obligations for the net discounted future cash flows for rental and associated costs at the cease-use date of $253,000 and a property and equipment impairment charge of $106,000.

*Other Income and (Expenses)*

The following table presents our net non-operating income and (expenses) for 2018 and 2017:

| Year Ended December 31, | | |
|---|---|---|
| 2018 | 2017 | % Change |
| (dollars in thousands) | | |
| $ 3,858 | $ 433 | 791% |

For 2018 and 2017, we recorded net non-operating income of $3.9 million and $433,000, respectively.

The principal source of non-operating income in 2018 was a bargain purchase gain of $6.8 million, representing the excess of our valuation of the fair value of net assets acquired over the fair value of the common stock issued to acquire them in the Merger.

Interest expense was $821,000 in 2018, decreasing from $3.0 million in 2017 due to Private Vaxart's convertible promissory notes being outstanding for only 43 days prior to the Merger, whereas they earned interest for 365 days in 2017. Non-cash interest expense on liability related to sale of future royalties of $1.9 million in 2018 relates to accounting for sums that will become payable to HCRP for royalty revenue earned from Inavir in the post-Merger period as debt.

The gain on revaluation of financial instruments in 2017 was principally caused by an embedded derivative liability related to the conversion feature on Private Vaxart's convertible promissory notes, which had a fair value of $3.3 million as of December 31, 2016, and zero as of December 31, 2017. Since Private Vaxart's convertible promissory notes and warrants converted to equity on the Merger, there are no longer any comparable financial instruments outstanding on which a change in fair value will be recorded.

The foreign exchange loss of $266,000 in 2018 relates to the revaluation of cash and receivables denominated in Australian dollars and British pounds at their December 31, 2018, exchange rates and resulted from the strengthening U.S. dollar.

*Provision for Income Taxes*

The following table presents our provision for income taxes for 2018 and 2017:

| Year Ended December 31, | | |
|---|---|---|
| 2018 | 2017 | % Change |
| (dollars in thousands) | | |
| $ 109 | $ — | N/A |

The provision for income taxes for 2018 comprises $102,000 of withholding tax on royalty revenue earned on sales of Inavir in Japan, which is potentially recoverable as a foreign tax credit but expensed because we record a 100% valuation allowance against our deferred tax assets, $4,000 relating to interest on an intercompany loan from a foreign subsidiary, plus $3,000 for state income taxes.

**Liquidity and Capital Resources**

Since inception, Private Vaxart's operations have been financed primarily by net proceeds of $38.9 million and $29.4 million from the sale of convertible preferred stock and the issuance of convertible promissory notes, respectively, all of which were converted into Aviragen common stock in the Merger, and $4.9 million from the issuance of secured promissory notes to Oxford Finance, repayable by January 2021. Vaxart gained $25.5 million in cash from Aviragen in the Merger, of which $4.9 million was used to pay for severance, financial advisory fees, director and officer insurance, legal and other professional costs incurred by Aviragen prior to, or upon the closing of, the Merger.

As of December 31, 2018, we had $11.5 million of cash and cash equivalents. We believe these funds, along with our projected revenue, are sufficient to fund us into, but possibly not beyond, the second quarter of 2019. Our independent auditors have included an explanatory paragraph in their report on our financial statements as of and for the year ended December 31, 2018, indicating that, because we have experienced losses and negative cash flows from operations and have an accumulated deficit and debt obligations, there is substantial doubt about our ability to continue as a going concern.

To continue operations thereafter, we will need to raise further capital, through the sale of additional securities or otherwise. Our operating needs include the planned costs to operate our business, including amounts required to fund working capital and capital expenditures. As of December 31, 2018, we had commitments for capital expenditures totaling $0.5 million. Our future capital requirements and the adequacy of our available funds will depend on many factors, most notably our ability to successfully commercialize our products and services.

We plan to continue to fund our operations and capital funding needs through equity and/or debt financing. We may also enter into government funding programs and consider selectively partnering for clinical development and commercialization. The sale of additional equity would result in additional dilution to our stockholders. Incurring debt financing would result in debt service obligations, and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market vaccine candidates that we would otherwise prefer to develop and market ourselves. Any of these actions could harm our business, results of operations and prospects.

Our future funding requirements will depend on many factors, including the following:

- the timing and costs of our planned clinical trials for our product candidates;
- the timing and costs of our planned preclinical studies of our product candidates;
- our success in establishing and scaling commercial manufacturing capabilities;
- the amount and timing of royalties received on sales of Relenza and Inavir;

- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking regulatory approvals;
- revenue received from commercial sales of our future products, which will be subject to receipt of regulatory approval;
- the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may enter into;
- the amount and timing of any payments that may be required in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or patent applications or other intellectual property rights; and
- the extent to which we in-license or acquire other products and technologies.

**Cash Flows**

The following table summarizes our cash flows for the periods indicated:

| | Year Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| | (in thousands) | |
| Cash used in operating activities | $ (14,548) | $ (10,040) |
| Cash provided by investing activities | 26,212 | 3,182 |
| Cash (used in) provided by financing activities | (1,729) | 24 |
| Net increase (decrease) in cash and cash equivalents | $ 9,935 | $ (6,834) |

*Net Cash Used in Operating Activities*

We experienced negative cash flow from operating activities in 2018 and 2017 in the amounts of $14.5 million and $10.0 million, respectively. The cash used in operating activities in 2018 was due to a net loss of $18.0 million, partially offset by $1.0 million of adjustments for net non-cash income related to the bargain purchase gain, depreciation and amortization, loss on sale of equipment, impairment charges, stock-based compensation, loss on revaluation of financial instruments, non-cash interest,amortization of note discount and non-cash interest expense and revenue related to sale of future royalties and $2.5 million provided by a change in working capital, principally due to the receipt of accounts receivable of $14.7 million acquired in the Merger. The cash used in operating activities in 2017 was due to cash used to fund a net loss of $9.6 million and a decrease in working capital of $624,000, partially offset by net non-cash expenses related to depreciation and amortization, gain on sale of equipment, stock-based compensation, amortization of discount on short-term investments, gain on revaluation of financial instruments, non-cash interest and amortization of note discount totaling $166,000.

*Net Cash Provided by Investing Activities*

In 2018 we received cash of $25.5 million in the Merger and $1.4 million from maturities of short-term investments, net of purchases. This was partially offset by $707,000 to purchase property and equipment and $21,000 to pay for fractional shares of common stock in the Merger. In 2017 Vaxart received $3.2 million from maturities of short-term investments, net of purchases, and $70,000 from the sale of equipment, partially offset by $117,000 used to purchase property and equipment.

*Net Cash (Used in) Provided by Financing Activities*

We used $1.5 million in 2018 to repay principal on the secured promissory note payable to Oxford Finance and $214,000 to repay principal on a short-term note, partially offset by $13,000 received upon the exercise of stock options. In 2017 we received $24,000 upon the exercise of stock options.

**Critical Accounting Policies and Estimates**

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially from these estimates. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

**Accrued Research and Development Expenses**

We record accrued expenses for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided and include the costs incurred but not yet invoiced within other accrued liabilities in the balance sheets and within research and development expense in the consolidated statements of operations and comprehensive loss. These costs can be a significant component of our research and development expenses.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates.

**Intangible Assets**

Intangible assets acquired in the Merger were recorded at their estimated fair values of $20.3 million and $1.8 million for developed technologies Inavir and Relenza, respectively, which are being amortized on a straight-line basis over the estimated periods of future royalties of 11.75 and 1.3 years, respectively, and $1.6 million for in-process research and development related to teslexivir which was considered indefinite-lived until it was assessed as impaired in the three months ended June 30, 2018. These valuations were prepared by an independent third party based on estimated discounted cash flows based on probability-weighted future development expenditures and revenue streams, which are highly subjective.

**Off-Balance Sheet Arrangements**

During 2017 and 2018, we did not have any off-balance sheet arrangements.

**Recently Issued Accounting Pronouncements**

See the “Recent Accounting Pronouncements” in Note 2 to the Consolidated Financial Statements in Part II, Item 8 for information related to the adoption of new accounting standards in 2018, none of which had a material impact on our financial statements, and the future adoption of recently issued accounting pronouncements, which we do not expect will have a material impact on our financial statements.

## Item 8. Financial Statements and Supplementary Data

## Report of Independent Registered Public Accounting Firm

The Stockholders and Board of Directors
Vaxart, Inc.

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Vaxart, Inc. and subsidiaries (the Company) as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the years in the two-year period ended December 31, 2018, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

**Going Concern**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has experienced losses and negative cash flows from operations since its inception, has an accumulated deficit, and has debt obligations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

*/s/ KPMG LLP*

We have served as the Company's auditor since 2014.

San Francisco, California
February 6, 2019

**VAXART, INC. AND SUBSIDIARIES**

**Consolidated Balance Sheets**
**(In thousands, except share and per share amounts)**

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 11,506 | $ 1,571 |
| Short-term investments | — | 1,415 |
| Accounts receivable | 1,796 | 630 |
| Prepaid expenses and other current assets | 1,343 | 137 |
| Total current assets | 14,645 | 3,753 |
| Property and equipment, net | 1,066 | 730 |
| Intangible assets, net | 19,413 | 40 |
| Other long-term assets | 103 | — |
| Total assets | $ 35,227 | $ 4,523 |
| **Liabilities and Stockholders' Equity (Deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 962 | $ 1,390 |
| Current portion of secured promissory note payable to Oxford Finance | 1,667 | 1,528 |
| Liability related to sale of future royalties, current portion | 3,328 | — |
| Other accrued current liabilities | 1,518 | 1,605 |
| Total current liabilities | 7,475 | 4,523 |
| Convertible promissory notes, long-term, related parties | — | 35,282 |
| Liability related to sale of future royalties, net of current portion | 14,413 | — |
| Secured promissory note payable to Oxford Finance, net of current portion | 1,944 | 3,440 |
| Other long-term liabilities | 157 | — |
| Total liabilities | 23,989 | 43,245 |
| Commitments and contingencies (Note 10) | | |
| Stockholders' equity (deficit): | | |
| Preferred Stock: $0.10 par value; 5,000,000 shares authorized; none issued and outstanding as of December 31, 2018; 1,221,064 issued and outstanding as of December 31, 2017, with aggregate liquidation value of $39,956 | — | 1 |
| Common Stock: $0.10 par value; 200,000,000 shares authorized; 7,141,189 and 138,492 shares issued and outstanding as of December 31, 2018 and 2017, respectively | 714 | — |
| Additional paid-in capital | 108,513 | 41,259 |
| Accumulated deficit | (97,989) | (79,982) |
| Total stockholders' equity (deficit) | 11,238 | (38,722) |
| Total liabilities and stockholders' equity (deficit) | $ 35,227 | $ 4,523 |

The accompanying notes are an integral part of these consolidated financial statements.

**VAXART, INC. AND SUBSIDIARIES**

**Consolidated Statements of Operations and Comprehensive Loss**
**(In thousands, except share and per share amounts)**

| | Year Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| Revenue: | | |
| Revenue from government contract | $ 1,344 | $ 5,839 |
| Royalty revenue | 1,340 | — |
| Non-cash royalty revenue related to the sale of future royalties | 1,475 | — |
| Total revenue | 4,159 | 5,839 |
| Operating expenses: | | |
| Research and development | 17,275 | 12,355 |
| General and administrative | 6,681 | 3,499 |
| Impairment of intangible assets | 1,600 | — |
| Costs of exit from leased premises | 359 | — |
| Total operating expenses | 25,915 | 15,854 |
| Operating loss | (21,756) | (10,015) |
| Other income and (expenses): | | |
| Bargain purchase gain | 6,760 | — |
| Interest income | 58 | 53 |
| Interest expense | (821) | (3,036) |
| Non-cash interest expense related to sale of future royalties | (1,859) | — |
| (Loss) gain on sale of equipment | (11) | 69 |
| (Loss) gain on revaluation of financial instruments, net | (3) | 3,347 |
| Foreign exchange loss, net | (266) | — |
| Total other income and (expenses) | 3,858 | 433 |
| Net loss before provision for income taxes | (17,898) | (9,582) |
| Provision for income taxes | 109 | — |
| Net loss | (18,007) | (9,582) |
| Series B and C preferred dividend | (339) | (2,878) |
| Net comprehensive loss attributable to common stockholders | $ (18,346) | $ (12,460) |
| Net loss per share – basic and diluted | $ (2.90) | $ (91.65) |
| Shares used to compute net loss per share – basic and diluted | 6,316,065 | 135,953 |

The accompanying notes are an integral part of these consolidated financial statements.

## VAXART, INC. AND SUBSIDIARIES

### Consolidated Statements of Stockholders' Equity (Deficit)
(In thousands, except share amounts)

| | Preferred Stock | | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | |
| Balances as of January 1, 2017 | 1,221,064 | $ 1 | 135,658 | $ — | $ 40,758 | $ (70,400) | $ (29,641) |
| Issuance of common stock upon exercise of stock options | — | — | 2,834 | — | 24 | — | 24 |
| Stock-based compensation | — | — | — | — | 477 | — | 477 |
| Net loss | — | — | — | — | — | (9,582) | (9,582) |
| Balances as of December 31, 2017 | 1,221,064 | $ 1 | 138,492 | $ — | $ 41,259 | $ (79,982) | $ (38,722) |
| Issuance of common stock upon conversion of convertible promissory notes, related parties | — | — | 1,571,702 | 157 | 35,420 | — | 35,577 |
| Issuance of common stock upon conversion of convertible preferred stock | (1,221,064) | (1) | 1,918,543 | 192 | (191) | — | — |
| Reclassification of warrant to equity | — | — | — | — | 70 | — | 70 |
| Issuance of common stock upon reverse merger | — | — | 3,510,439 | 365 | 31,403 | — | 31,768 |
| Issuance of common stock upon exercise of stock options | — | — | 2,013 | — | 13 | — | 13 |
| Stock-based compensation | — | — | — | — | 539 | — | 539 |
| Net loss | — | — | — | — | — | (18,007) | (18,007) |
| Balances as of December 31, 2018 | — | $ — | 7,141,189 | $ 714 | $ 108,513 | $ (97,989) | $ 11,238 |

The accompanying notes are an integral part of these consolidated financial statements.

## VAXART, INC. AND SUBSIDIARIES

### Consolidated Statements of Cash Flows
(In thousands)

| | Year Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| Cash flows from operating activities: | | |
| Net loss | $ (18,007) | $ (9,582) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Bargain purchase gain | (6,760) | — |
| Depreciation and amortization | 3,203 | 380 |
| Loss (gain) on sale of equipment | 11 | (69) |
| Impairment of intangible assets | 1,600 | — |
| Impairment of property and equipment | 106 | — |
| Stock-based compensation | 539 | 477 |
| Amortization of discount on short-term investments | — | 24 |
| Loss (gain) on revaluation of financial instruments, net | 3 | (3,347) |
| Non-cash interest expense | 448 | 2,557 |
| Amortization of note discount | 18 | 144 |
| Non-cash interest expense related to sale of future royalties | 1,859 | — |
| Non-cash revenue related to sale of future royalties | (18) | — |
| Change in operating assets and liabilities: | | |
| Accounts receivable | 13,500 | 960 |
| Prepaid expenses and other assets | (873) | 52 |
| Accounts payable | (3,784) | (1,559) |
| Accrued liabilities | (6,393) | (77) |
| Net cash used in operating activities | (14,548) | (10,040) |
| Cash flows from investing activities: | | |
| Purchase of property and equipment | (707) | (117) |
| Proceeds from sale of equipment | — | 70 |
| Cash acquired in reverse merger | 25,525 | — |
| Cash paid for fractional shares in merger | (21) | — |
| Purchases of short-term investments | (573) | (7,351) |
| Proceeds from maturities of short-term investments | 1,988 | 10,580 |
| Net cash provided by investing activities | 26,212 | 3,182 |
| Cash flows from financing activities: | | |
| Repayment of principal on secured promissory note payable to Oxford Finance | (1,528) | — |
| Repayment of short-term note | (214) | — |
| Proceeds from issuance of common stock upon exercise of stock options | 13 | 24 |
| Net cash (used in) provided by financing activities | (1,729) | 24 |
| Net increase (decrease) in cash and cash equivalents | 9,935 | (6,834) |
| Cash and cash equivalents at beginning of the period | 1,571 | 8,405 |
| Cash and cash equivalents at end of the period | $ 11,506 | $ 1,571 |

The accompanying notes are an integral part of these consolidated financial statements.

## VAXART, INC. AND SUBSIDIARIES

**Consolidated Statements of Cash Flows (continued)**
**(In thousands)**

| | Year Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| **Supplemental disclosure of cash flow information:** | | |
| Interest paid | $ 356 | $ 335 |
| **Supplemental disclosure of non-cash investing and financing activity:** | | |
| Issuance of common stock upon reverse merger, net of cash paid for partial shares | $ 31,768 | $ — |
| Conversion of convertible promissory notes, related parties into common stock upon reverse merger | $ 35,577 | $ — |
| Reclassification of convertible preferred stock warrant liability to equity | $ 70 | $ — |
| Acquisition of property and equipment included in accounts payable | $ 52 | $ — |

The accompanying notes are an integral part of these consolidated financial statements.

**VAXART, INC. AND SUBSIDIARIES**

**Notes to the Consolidated Financial Statements**

## NOTE 1. Organization and Basis of Presentation

*General*

Vaxart Biosciences, Inc. was originally incorporated in California in March 2004, under the name West Coast Biologicals, Inc. The Company changed its name to Vaxart, Inc. ("Private Vaxart") in July 2007, and reincorporated in the state of Delaware.

On February 13, 2018, Private Vaxart completed a business combination with Aviragen Therapeutics, Inc. ("Aviragen"), pursuant to which Aviragen merged with Private Vaxart, with Private Vaxart surviving as a wholly-owned subsidiary of Aviragen (the "Merger"). Pursuant to the terms of the Merger, Aviragen changed its name to Vaxart, Inc. (together with its subsidiaries, the "Company" or "Vaxart") and Private Vaxart changed its name to Vaxart Biosciences, Inc . All of Private Vaxart's convertible promissory notes and convertible preferred stock was converted into common stock, following which each share of common stock was converted into approximately 0.22148 shares of the Company's common stock (the "Conversion"). Except as otherwise noted in these Financial Statements, all shares, equity securities and per share amounts of Private Vaxart are presented to give retroactive effect to the Conversion.

Immediately following the completion of the Merger, the Company effected a reverse stock split at a ratio of one new share for every eleven shares of the Company's common stock outstanding (the "Reverse Stock Split").Except as otherwise noted in these Financial Statements, all share, equity security and per share amounts are presented to give retroactive effect to the Reverse Stock Split.

Immediately after the Reverse Stock Split there were approximately 7.1 million shares of the Company's common stock outstanding. Private Vaxart's stockholders, warrantholders and optionholders owned approximately 51% of the fully-diluted common stock of the Company, with Aviragen's stockholders and optionholders immediately prior to the Merger owning approximately 49% of the fully-diluted common stock of the Company. The Company also assumed all of Private Vaxart's outstanding stock options and warrants with proportionate adjustments to the number of underlying shares and exercise prices based on an exchange ratio, based on the combined impact of the Conversion and the Reverse Stock Split, of approximately 0.0201346 shares of the Company for each share of Private Vaxart.

The Company's principal operations are based in South San Francisco, California, and it operates in one reportable segment, which is the discovery and development of oral recombinant protein vaccines, based on its proprietary oral vaccine platform.

*Liquidity and Going Concern*

Since incorporation, the Company has been involved primarily in performing research and development activities, hiring personnel, and raising capital to support these activities. The Company has experienced losses and negative cash flows from operations since its inception. As of December 31, 2018, the Company had an accumulated deficit of $98.0 million and a loan with an outstanding balance of $3.6 million from Oxford Finance, LLC ("Oxford Finance"), repayable in monthly installments by January 2021 (see Note 9).

The Company expects to incur increasing costs as research and clinical trials are advanced and, therefore, expects to continue to incur losses and negative operating cash flows for the next several years. Absent additional funding or adjustments to currently planned operating activities, and in view of the uncertainties regarding future royalty revenue on sales of Relenza and Inavir, management believes that the Company's cash and cash equivalents of $11.5 million held as of December 31, 2018, are sufficient to fund the Company into, but possibly not beyond, the second quarter of 2019.

The Company reviews its operations and clinical plans on a continuing basis, including its commitments for upcoming clinical trials. The Company plans to finance its operations with royalty revenue on sales of Relenza and Inavir, additional equity or debt financing arrangements, and potentially with additional funding from government contracts or strategic alliances with partner companies. The availability and amount of such funding is not certain.

The uncertainties inherent in the Company's future operations and in its ability to obtain additional funding raise substantial doubt about its ability to continue as a going concern beyond one year from the date these financial statements are issued. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**VAXART, INC. AND SUBSIDIARIES**

**Notes to the Consolidated Financial Statements**

While management believes its plan to raise additional funds will alleviate the conditions that raise substantial doubt, these plans are not entirely within its control and cannot be assessed as being probable of occurring. If adequate funds are not available, the Company may be required to reduce operating expenses, delay or reduce the scope of its product development programs, obtain funds through arrangements with others that may require the Company to relinquish rights to certain of its technologies or products that the Company would otherwise seek to develop or commercialize itself, or cease operations.

**NOTE 2. Summary of Significant Accounting Policies**

**Basis of Presentation** – The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

**Basis of Consolidation** – The consolidated financial statements include the financial statements of Vaxart, Inc. and its subsidiaries. All significant transactions and balances between Vaxart, Inc. and its subsidiaries have been eliminated in consolidation.

**Use of Estimates** – The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and disclosure of contingent assets and liabilities in the financial statements and accompanying notes. Actual results and outcomes could differ from these estimates and assumptions.

**Foreign Currencies** – Foreign exchange gains and losses for assets and liabilities of the Company's non-U.S. subsidiaries for which the functional currency is the U.S. dollar are recorded in foreign exchange gain or loss, net within other income and (expenses) in the Company's statements of operations and comprehensive loss. The Company has no subsidiaries for which the local currency is the functional currency.

**Cash and Cash Equivalents** – The Company considers all highly liquid debt investments with an original maturity of three months or less when purchased to be cash equivalents. Cash equivalents, which may consist of amounts invested in money market funds, corporate bonds and commercial paper, are stated at fair value. Cash and cash equivalents as of December 31, 2018 and 2017, includes $50,000 of restricted cash.

**Short-Term Investments** – The Company's short-term investments have only comprised commercial paper and corporate bonds. The short-term investments are classified as held-to-maturity based on the Company's positive intent and ability to hold the securities to maturity. This classification is reevaluated at each balance sheet date. Short-term investments are stated at amortized cost, adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is presented as interest income in the statement of operations and comprehensive loss. The specific identification method is used to determine the realized gain or loss on securities sold or otherwise disposed. When the fair value of a debt security classified as held-to-maturity is less than its amortized cost, the Company assesses whether or not: (i) it has the intent to sell the security or (ii) it is more likely than not that the Company will be required to sell the security before its anticipated recovery. If either of these conditions is met, the Company must recognize an other-than-temporary impairment through earnings for the difference between the debt security's amortized cost basis and its fair value. Gains and losses are recognized in earnings when the investments are sold or impaired.

**Concentration of Credit Risk** – Financial instruments that potentially subject the Company to significant concentrations of credit risk consist principally of cash, cash equivalents, short-term investments and accounts receivable. The Company places its cash, cash equivalents and short-term investments at financial institutions that management believes are of high credit quality. The Company is exposed to credit risk in the event of default by the financial institutions holding the cash and cash equivalents to the extent such amounts are in excess of the federally insured limits. The Company has not experienced any losses on its deposits since inception.

The primary focus of the Company's investment strategy is to preserve capital and meet liquidity requirements. The Company's investment policy addresses the level of credit exposure by limiting the concentration in any one corporate issuer or sector and establishing a minimum allowable credit rating. The Company generally requires no collateral from its customers.

**VAXART, INC. AND SUBSIDIARIES**

**Notes to the Consolidated Financial Statements**

**Accounts Receivable** – Accounts receivable arise from the Company's royalty revenue receivable for sales, net of estimated returns, of Inavir and Relenza, and from its contract with the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority ("HHS BARDA") (see Note 6), and are reported at amounts expected to be collected in future periods. An allowance for uncollectible accounts will be recorded based on a combination of historical experience, aging analysis, and information on specific accounts, with related amounts recorded as a reserve against revenue recognized. Account balances will be written off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. The Company has provided no allowance for uncollectible accounts as of December 31, 2018 and 2017.

**Property and Equipment** – Property and equipment is carried at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets. Depreciation begins at the time the asset is placed in service. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in other income and (expenses) in the period realized.

The useful lives of the property and equipment are as follows:

| | |
|---|---|
| Laboratory equipment | 5 years |
| Office and computer equipment | 3 years |
| Leasehold improvements | Shorter of remaining lease term or estimated useful life |

**Intangible Assets** – Intangible assets comprise developed technology, intellectual property and, until it was considered fully impaired (see Note 5), in-process research and development. Intangible assets are carried at cost less accumulated amortization. Amortization is computed using the straight-line method over useful lives ranging from 1.3 to 11.75 years for developed technology and 20 years for intellectual property. In-process research and development is considered to be indefinite-lived and is not amortized, but is subject to impairment testing. The Company assessed its in-process research and development as fully impaired in the year ended December 31, 2018 (see Note 5).

**Impairment of Long-Lived Assets** – The Company reviews its long-lived assets, including property and equipment and intangible assets with finite lives, for impairment whenever events or changes in circumstances indicate the carrying amount of these assets may not be recoverable. Recoverability of these assets is measured by comparison of the carrying amount of each asset to the future undiscounted cash flows the asset is expected to generate over its remaining life. When indications of impairment are present and the estimated undiscounted future cash flows from the use of these assets is less than the assets' carrying value, the related assets will be written down to fair value. The Company assessed leasehold improvements and furniture at its leased offices in Alpharetta, Georgia as impaired in the year ended December 31, 2018 (see Notes 5 and 10). There have been no other impairments of the Company's long-lived assets for the periods presented.

**Accrued Clinical and Manufacturing Expenses** – The Company accrues for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided and includes the costs incurred but not yet invoiced within other accrued liabilities in the balance sheets and within research and development expense in the consolidated statements of operations and comprehensive loss. These costs can be a significant component of the Company's research and development expenses.

The Company estimates the amount of services provided through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. The Company makes significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, it adjusts its accrued estimates. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed, the number of subjects enrolled, and the rate of enrollment may vary from its estimates and could result in the Company reporting amounts that are too high or too low in any particular period. The Company's accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from contract research organizations and other third-party service providers. To date, the Company has not experienced any material differences between accrued costs and actual costs incurred.

**VAXART, INC. AND SUBSIDIARIES**

**Notes to the Consolidated Financial Statements**

**Convertible Preferred Stock Warrant Liability** – The Company has issued certain convertible preferred stock warrants. These warrants were recorded within other accrued liabilities in the balance sheets at fair value due to down-round protection features contained in the convertible preferred stock into which the warrants were exercisable. At the end of each reporting period, changes in fair value of the warrants since the prior period were recorded as a component of (loss) gain on revaluation of financial instruments, net within other income and (expenses) in the consolidated statements of operations and comprehensive loss. In the event that the terms of the warrant change such that liability accounting is no longer required, the fair value on the date of such change is released to equity.

**Convertible Promissory Notes Embedded Derivative Liability** – The Company recorded derivative instruments related to redemption features embedded within the outstanding convertible promissory notes. The embedded derivatives were accounted for as liabilities at their estimated fair value when the convertible promissory notes were issued and were re-measured to fair value as of each balance sheet date, with the related re-measurement adjustment being recognized as a component of (loss) gain on revaluation of financial instruments in the consolidated statements of operations and comprehensive loss.

**Revenue Recognition** – The Company recognizes revenue when it transfers control of promised goods or services to its customers, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition, the Company performs the following five steps:

(i) identification of the promised goods or services in the contract;

(ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;

(iii) measurement of the transaction price, including the constraint on variable consideration;

(iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and

(v) recognition of revenue when (or as) the Company satisfies each performance obligation. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account.

Revenue from royalties earned as a percentage of sales, including milestone payments based on achieving a specified level of sales, where a license is deemed to be the predominant item to which the royalties relate, is recognized as revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied), as required under the sales- and usage-based royalty exception.

The Company performed research and development work under its cost-plus-fixed-fee contract with HHS BARDA. The Company recognizes revenue under research contracts only when a contract has been executed and the contract price is fixed or determinable. Revenue from the HHS BARDA contract is recognized in the period during which the related costs are incurred and the related services are rendered, provided that the applicable conditions under the contract have been met. Costs of contract revenue are recorded as a component of operating expenses in the consolidated statements of operations and comprehensive loss.

Under the cost reimbursable contract with HHS BARDA, the Company is reimbursed for allowable costs, and recognizes revenue as allowable costs are incurred and the fixed-fee is earned. Reimbursable costs under the contract primarily include direct labor, subcontract costs, materials, equipment, travel, and approved overhead and indirect costs. Fixed fees under cost reimbursable contracts are earned in proportion to the allowable costs incurred in performance of the work relative to total estimated contract costs, with such costs incurred representing a reasonable measurement of the proportional performance of the work completed. Under the HHS BARDA contract, certain activities must be pre-approved in order for their costs to be deemed allowable direct costs. The HHS BARDA contract provides the U.S. government the ability to terminate the contract for convenience or to terminate for default if the Company fails to meet its obligations as set forth in the statement of work.

Payments to the Company under cost reimbursable contracts, such as this contract, are provisional payments subject to adjustment upon annual audit by the government. Management believes that revenue for periods not yet audited has been recorded in amounts that are expected to be realized upon final audit and settlement. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly in the period that the adjustment is known.

**Research and Development Costs** – Research and development costs are expensed as incurred. Research and development costs consist primarily of salaries and benefits, stock-based compensation, consultant fees, third-party costs for conducting clinical trials and the manufacture of clinical trial materials, certain facility costs and other costs associated with clinical trials. Payments made to other entities are under agreements that are generally cancelable by the Company. Advance payments for research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related services are performed.

**VAXART, INC. AND SUBSIDIARIES**

**Notes to the Consolidated Financial Statements**

**Stock-Based Compensation** – The Company measures the fair value of all stock-based awards, including stock options, to employees and, since April 1, 2018, to nonemployees, on the grant date and records the fair value of these awards, net of estimated forfeitures, to compensation expense over the service period. Prior to April 1, 2018, the fair value of awards to nonemployees was measured on the date of performance at the fair value of the consideration received or the fair value of the equity instruments issued, whichever was more reliably measured. The fair value of options is estimated using the Black-Scholes valuation model. The expected term of each option is estimated by taking the arithmetic average of its original contractual term and its average vesting term.

**Net Income (Loss) Per Share Attributable to Common Stockholders** – Basic net income (loss) per share is computed by dividing net income (loss), as adjusted for dividends on the Series B and Series C convertible preferred stock in the period, by the weighted average number of common shares outstanding during the period, without consideration of potential common shares.

Diluted net income (loss) per common share is computed giving effect to all potential dilutive common shares, comprising common stock issuable upon exercise of stock options and warrants. The Company uses the treasury-stock method to compute diluted income (loss) per share with respect to its stock options and warrants. For purposes of this calculation, options and warrants to purchase common stock are considered to be potential common shares and are only included in the calculation of diluted net income per share when their effect is dilutive. In the event of a net loss, the effects of all potentially dilutive shares are excluded from the diluted net loss per share calculation as their inclusion would be antidilutive.

**Recently Adopted Accounting Pronouncements**

In June 2018, the FASB issued ASU 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. This update simplifies the accounting for share-based payment transactions by changing the guidance for accounting for nonemployee share-based awards so that, instead of revaluing each award at each balance sheet date during the period over which it vests, the value will be fixed on the grant date and expensed over the vesting period in the same way that employee awards are already accounted for. This guidance is effective for annual periods beginning after December 15, 2018, including interim periods within that year, with early adoption permitted for entities that had already adopted Topic 606 (see ASU 2014-09 below). The Company adopted ASU 2018-07 effective April 1, 2018, and since it had no unvested awards granted to nonemployees, its adoption had no effect on the Company's financial condition or results of operations.

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting*. This update provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. This guidance is effective for annual periods beginning after December 15, 2017, including interim periods within that year, and must be applied prospectively to an award modified on or after the adoption date. The Company adopted this standard effective January 1, 2018, and its adoption had no effect on the Company's financial condition or results of operations.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles-Goodwill and Other (Topic 350) Simplifying the Test for Goodwill Impairment* ("ASU 2017-04"), which will simplify the goodwill impairment calculation by eliminating Step 2 from the current goodwill impairment test. The new standard does not change how a goodwill impairment is identified. The standard will be effective January 1, 2020, with early adoption permitted, and is to be applied prospectively from the date of adoption. The Company adopted this standard effective January 1, 2018, and its adoption had no effect on the Company's financial condition or results of operations.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805) Clarifying the Definition of a Business* ("ASU 2017-01"). The new standard clarifies the definition of a business to help companies evaluate whether acquisition or disposal transactions should be accounted for as asset groups or as businesses. The Company adopted this standard when it became effective on January 1, 2018, and it was applied in connection with the Company's accounting for the Merger as a business combination.

In August 2016, the FASB issued Accounting Standards Update (ASU) 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which provides additional guidance on the presentation and classification of certain items in the statement of cash flows. The standard is effective for fiscal years beginning after December 15, 2017, with early adoption permitted. The Company adopted this standard effective January 1, 2018, and its adoption had no effect on the Company's financial condition or results of operations.

**VAXART, INC. AND SUBSIDIARIES**

**Notes to the Consolidated Financial Statements**

In May 2014, the FASB issued ASU 2014-09 , *Revenue from Contracts with Customers (Topic 606)*, which supersedes nearly all existing revenue recognition guidance under Topic 605, *Revenue Recognition*. The new standard requires a company to recognize revenue when it transfers goods and services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. ASU 2014-09 defines a five-step process that includes identifying the contract with the customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations in the contract and recognizing revenue when (or as) the entity satisfies the performance obligations.

The Company has determined that its HHS BARDA government contract is not within the scope of ASU 2014-09 as the government entity is not a customer under the agreement. The Company adopted ASU 2014-09 with respect to its royalty revenue using the modified retrospective method on January 1, 2018. Under the modified retrospective transition method, the cumulative effect of applying the standard is recognized at the date of initial application for all contracts not completed as of the date of adoption. The adoption of ASU 2014-09 did not have any effect on the Company's financial condition or results of operations and therefore no cumulative effect adjustment was recorded, although the Company has modified its accounting policies to reflect the requirements of this standard and make additional disclosures.

**Recent Accounting Pronouncements**

In February 2016, the FASB issued ASU 2016-02 *Leases (Topic 842)*, which replaces most current lease guidance when it becomes effective. This standard update intends to increase transparency and improve comparability by requiring entities to recognize assets and liabilities on the balance sheet for all leases, with certain exceptions. The new standard states that a lessee will recognize a lease liability for the obligation to make lease payments and a right-of-use asset for the right to use the underlying asset for the lease term. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the statements of operations. The new guidance will be effective for the Company starting in the first quarter of fiscal 2019, with early adoption permitted. The Company plans to adopt the new guidance effective January 1, 2019, using the modified retrospective method, and to use the effective date method of adoption, as permitted by ASU 2018-11, *Targeted Improvements*, which the FASB issued in July 2018, which reduces the disclosure requirements on transition. The Company has elected the short-term lease recognition exemption for all classes of assets, which means that it will not recognize right-of-use assets or lease liabilities for leases with a duration of one year or less. Further, the Company has elected to use all of the practical expedients available on transition, whereby it has not reassessed under the new standard its prior conclusions about lease identification, lease classification and initial direct costs.

We expect that this standard will have a material effect on our consolidated financial statements. The most significant effects relate to the recognition of new right-of-use assets and lease liabilities on our consolidated balance sheet. The Company currently expects to recognize lease liabilities of $1,207,000, $766,000 of which is current, and right-of-use assets of $941,000 based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases, to derecognize liabilities of $239,000, $100,000 of which is current, and recognize an increase of $27,000 to accumulated deficit on adoption of the new accounting policy.

The increase in accumulated deficit arises because the right-of-use asset impairment charge that would have been recorded in the three months ended December 31, 2018, under Topic 842 exceeds the lease loss accrual, net of accretion, that was recorded (see Note 10). This impact aside, the adoption will have no effect on the Company's statements of operations or cash flows, other than on related disclosures.

The Company has reviewed all other significant newly-issued accounting pronouncements and concluded that they either are not applicable to the Company's operations or no material effect is expected on its consolidated financial statements as a result of future adoption.

VAXART, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

**NOTE 3. Business Combination**

On February 13, 2018, the Company acquired Aviragen in a reverse merger (see Note 1). On the date of the Merger, Aviragen had in-process research and development as it was conducting a Phase 2 trial, it had previously developed drugs that were licensed to others who brought them to market and it had a workforce that was considered to have the necessary skills, knowledge, and experience to perform a process that, when applied to the in-process research and development, was critical to the ability to convert it into outputs. Based on this evaluation, the Company determined that the Merger should be accounted for as a business combination.

Since the date of the Merger, the results of Aviragen's operations have been included in the consolidated financial statements. As a result of the acquisition, the Company eliminated the majority of its debt and acquired a significant cash balance in exchange for equity securities.

The total purchase price for Aviragen is summarized as follows (in thousands):

| | |
|---|---|
| Common stock | $ 31,789 |
| Total | $ 31,789 |

In connection with the Aviragen acquisition, the Company allocated the total purchase consideration to the net assets and liabilities acquired, including identifiable intangible assets, based on their respective fair values at the acquisition date.

The following table summarizes the preliminary allocation of the purchase price to the fair value of the respective assets and liabilities acquired, adjustments made since the acquisition date and the final allocation as of December 31, 2018:

| | As of February 13, 2018 | Adjustments | As of December 31, 2018 |
|---|---|---|---|
| | | (in thousands) | |
| Cash and cash equivalents | $ 25,525 | $ — | $ 25,525 |
| Accounts receivable | 14,666 | — | 14,666 |
| Prepaid expenses | 446 | (10) | 436 |
| Property and equipment | 170 | — | 170 |
| Intangible assets: | | | |
| Developed technology (1) | 22,400 | (300) | 22,100 |
| In-process research and development (2) | 1,600 | — | 1,600 |
| Total assets | 64,807 | (310) | 64,497 |
| | | | |
| Accounts payable | (3,379) | 75 | (3,304) |
| Other current liabilities | (6,351) | (393) | (6,744) |
| Liability related to sale of future royalties | (16,300) | 400 | (15,900) |
| Net assets acquired | 38,777 | (228) | 38,549 |
| | | | |
| Purchase price | (31,789) | — | (31,789) |
| | | | |
| Bargain purchase gain (3) | $ 6,988 | $ (228) | $ 6,760 |

(1) Developed technology comprises Inavir and Relenza, both influenza vaccines on which the Company is presently receiving royalty revenue, which, based on valuations prepared by an independent third party based on estimated discounted cash flows based on probability-weighted future development expenditures and revenue streams provided by the Company's management, are being amortized on a straight-line basis over the estimated periods of future royalties of 11.75 and 1.3 years, respectively.

(2) In-process research and development (see Note 5) related to teslexivir, or BTA074, a direct-acting antiviral that, at the time of the Merger, was being actively developed as a treatment for genital warts. The valuation was prepared by an independent third party based on estimated discounted cash flows based on probability-weighted future development expenditures and revenue streams provided by the Company's management.

(3) The bargain purchase gain represents the excess of the fair value of tangible and identified intangible assets, less liabilities, acquired over the purchase price.

**VAXART, INC. AND SUBSIDIARIES**

**Notes to the Consolidated Financial Statements**

In addition, the Company incurred and expensed costs directly related to the Merger totaling approximately $0.5 million and $0.9 million in the years ended December 31, 2018 and 2017, respectively, which are included in general and administrative expenses in the consolidated statement of operations and comprehensive loss.

Selected amounts related to Aviragen's business included in the Company's consolidated statement of operations for the year ended December 31, 2018, are as follows (in thousands):

| | | |
|---|---|---|
| Revenue | $ | 2,815 |
| Net loss | $ | (3,847) |

The unaudited pro forma information in the table below summarizes the combined results of operations of Vaxart Biosciences, Inc. with those of Aviragen as though these entities were combined as of January 1, 2017. The results of Aviragen's business for the year ended December 31, 2017, are based on information used to prepare its audited consolidated financial statements prepared for the year ended June 30, 2017, as adjusted by information used to prepare its unaudited condensed consolidated financial statements prepared for the six months ended December 31, 2017 and 2016. The results of Aviragen's business for the year ended December 31, 2018, are based on the Company's results of operations, with the results increased by Aviragen's activities in the forty-three days prior to the closing of the Merger. The pro forma financial information for both years presented also includes the removal of direct acquisition-related costs, the reduction in interest expense on borrowing converted into equity in the reverse merger, and the actual depreciation and amortization that would have been charged assuming the fair value adjustments to property and equipment and intangible assets had been applied as of January 1, 2017.

This unaudited pro forma information is summarized as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| | (in thousands) | |
| Total revenue | $ 15,695 | $ 13,527 |
| Net loss | $ (13,162) | $ (29,270) |

The pro forma financial information as presented above is for informational purposes only and is not indicative of the consolidated results of operations of future periods or the results of operations that would have been achieved had the acquisition had taken place on January 1, 2017.

**NOTE 4. Fair Value of Financial Instruments**

Fair value accounting is applied for all financial assets and liabilities and nonfinancial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). Financial instruments include cash and cash equivalents, short-term investments, accounts receivable, accounts payable and accrued liabilities that approximate fair value due to their relatively short maturities. As short-term investments are classified as held-to-maturity, they are recorded at their amortized cost.

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with inputs used to measure their fair values. The accounting guidance for fair value provides a framework for measuring fair value and requires certain disclosures about how fair value is determined. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance also establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity.

The three-level hierarchy for the inputs to valuation techniques is briefly summarized as follows:

VAXART, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

Level 1 – Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2 – Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3 – Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

The Company's money market funds are classified within Level 1 of the fair value hierarchy and are valued based on quoted prices in active markets for identical securities. The Company's corporate bonds and commercial paper are classified within Level 2 of the fair value hierarchy and are valued based on quoted prices for similar assets or prices derived from observable market data. Level 3 liabilities consist of convertible promissory notes embedded derivative liabilities and a convertible preferred stock warrant liability as they are valued by using inputs that are unobservable in the market. The determination of the fair values of the convertible promissory notes embedded derivative is discussed in Note 8.

The following tables present the Company's financial assets and liabilities that are measured at fair value at December 31, 2018 and 2017:

| December 31, 2018 | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| | | (in thousands) | | |
| Recurring Financial Assets: | | | | |
| Money Market Funds | $ 15 | $ — | $ — | $ 15 |
| Corporate Bonds | — | — | — | — |
| Total assets | $ 15 | $ — | $ — | $ 15 |
| Recurring Financial Liabilities: | | | | |
| Convertible promissory notes embedded derivative liability | $ — | $ — | $ — | $ — |
| Convertible preferred stock warrant liability | — | — | — | — |
| Total liabilities | $ — | $ — | $ — | $ — |

| December 31, 2017 | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| | | (in thousands) | | |
| Recurring Financial Assets: | | | | |
| Money Market Funds | $ 1,192 | $ — | $ — | $ 1,192 |
| Corporate Bonds | — | 1,415 | — | 1,415 |
| Total assets | $ 1,192 | $ 1,415 | $ — | $ 2,607 |
| Recurring Financial Liabilities: | | | | |
| Convertible promissory notes embedded derivative liability | $ — | $ — | $ — | $ — |
| Convertible preferred stock warrant liability | — | — | 67 | 67 |
| Total liabilities | $ — | $ — | $ 67 | $ 67 |

VAXART, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

The following tables present a reconciliation of all liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the years ended December 31, 2018 and 2017:

| | Convertible Preferred Stock Warrant Liability | Convertible Promissory Notes Embedded Derivative Liability | Total |
|---|---|---|---|
| | | (in thousands) | |
| Balance at January 1, 2018 | $ 67 | $ — | $ 67 |
| Issuances | — | — | — |
| Revaluation loss included in (loss) gain on revaluation of financial instruments, net | 3 | — | 3 |
| Settlements | (70) | — | (70) |
| Balance at December 31, 2018 | $ — | $ — | $ — |
| | | | |
| Total losses included in other income and (expenses) attributable to liabilities still held as of December 31, 2018 | $ — | $ — | $ — |

| | Convertible Preferred Stock Warrant Liability | Convertible Promissory Notes Embedded Derivative Liability | Total |
|---|---|---|---|
| | | (in thousands) | |
| Balance at January 1, 2017 | $ 134 | $ 3,280 | $ 3,414 |
| Issuances | — | — | — |
| Revaluation gains included in (loss) gain on revaluation of financial instruments, net | (67) | (3,280) | (3,347) |
| Settlements | — | — | — |
| Balance at December 31, 2017 | $ 67 | $ — | $ 67 |
| | | | |
| Total gains included in other income and (expenses) attributable to liabilities still held as of December 31, 2017 | $ 67 | $ 3,280 | $ 3,347 |

**NOTE 5. Balance Sheet Components**

***(a) Cash Equivalents and Short-Term Investments***

Cash equivalents and short-term investments, all of which are classified as held-to-maturity securities and mature within one year, consisted of the following:

| | December 31, 2018 | | | | |
|---|---|---|---|---|---|
| | Amortized Cost | Gross Unrecognized Gains | Gross Unrecognized Losses | Estimated Fair Value | Carrying Value |
| | | | (in thousands) | | |
| Money market funds | $ 15 | $ — | $ — | $ 15 | $ 15 |
| Corporate bonds | — | — | — | — | — |
| Total | $ 15 | $ — | $ — | $ 15 | $ 15 |
| Reported as: | | | | | |
| Cash equivalents | $ 15 | $ — | $ — | $ 15 | $ 15 |
| Short-term investments | — | — | — | — | — |
| Total | $ 15 | $ — | $ — | $ 15 | $ 15 |

VAXART, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

| | December 31, 2017 | | | | |
|---|---|---|---|---|---|
| | Amortized Cost | Gross Unrecognized Gains | Gross Unrecognized Losses | Estimated Fair Value | Carrying Value |
| | | | (in thousands) | | |
| Money market funds | $ 1,192 | $ — | $ — | $ 1,192 | $ 1,192 |
| Corporate bonds | 1,415 | — | — | 1,415 | 1,415 |
| Total | $ 2,607 | $ — | $ — | $ 2,607 | $ 2,607 |
| Reported as: | | | | | |
| Cash equivalents | $ 1,192 | $ — | $ — | $ 1,192 | $ 1,192 |
| Short-term investments | 1,415 | — | — | 1,415 | 1,415 |
| Total | $ 2,607 | $ — | $ — | $ 2,607 | $ 2,607 |

***(b) Accounts Receivable***

Accounts receivable comprises the following:

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| | (in thousands) | |
| Royalties receivable | $ 1,776 | $ — |
| Government contract – billed | 20 | 477 |
| Government contract – unbilled | — | 153 |
| Accounts receivable | $ 1,796 | $ 630 |

***(c) Property and Equipment, Net***

Property and equipment, net consists of the following:

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| | (in thousands) | |
| Laboratory equipment | $ 2,076 | $ 1,565 |
| Office and computer equipment | 227 | 175 |
| Leasehold improvements | 333 | 226 |
| Total property and equipment | 2,636 | 1,966 |
| Less: accumulated depreciation | (1,570) | (1,236) |
| Property and equipment, net | $ 1,066 | $ 730 |

Depreciation expense was $476,000 and $376,000 for the years ended December 31, 2018 and 2017, respectively. Leasehold improvements and furniture at the Company's leased premises in Georgia, which has been subleased, commencing in November 2018, for less than the rental that the Company is obligated to pay (see Note 10), were assessed as impaired as of September 30, 2018, and accordingly an impairment charge of $106,000 was recorded as a component of costs of exit from leased premises within operating expenses.

*(d) Intangible Assets*

Intangible assets consist of the following:

| | December 31, 2018 | February 13, 2018 | December 31, 2017 |
|---|---|---|---|
| | | (in thousands) | |
| Purchased technology | $ 22,100 | $ 22,400 | $ — |
| In-process research and development | — | 1,600 | — |
| Intellectual property | 80 | 80 | 80 |
| Total cost | 22,180 | 24,080 | 80 |
| Less accumulated amortization | 2,767 | 40 | 40 |
| Intangible assets, net | $ 19,413 | $ 24,040 | $ 40 |

Intangible asset amortization expense was $2,727,000 and $4,000 for the years ended December 31, 2018 and 2017, respectively. Following the results of Phase 2 trials in June 2018, the in-process research and development was assessed as fully impaired in the three months ended June 30, 2018, with the $1.6 million acquired in the Merger (see Note 3) being charged to operating expenses.

As of December 31, 2018, the estimated future amortization expense by year is as follows (in thousands):

| Year Ending December 31, | |
|---|---|
| 2019 | $ 2,320 |
| 2020 | 1,732 |
| 2021 | 1,732 |
| 2022 | 1,732 |
| 2023 | 1,731 |
| Thereafter | 10,166 |
| Total | $ 19,413 |

*(e) Other Accrued Liabilities*

Accrued liabilities consist of the following:

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| | (in thousands) | |
| Accrued compensation | $ 632 | $ 1,320 |
| Accrued clinical and manufacturing expenses | 75 | 69 |
| Accrued professional and consulting services | 166 | 113 |
| Reserve for return of royalties | 339 | — |
| Deferred rent and lease loss accrual, current portion | 111 | 21 |
| Convertible preferred stock warrant liability | — | 67 |
| Other | 195 | 15 |
| Total | $ 1,518 | $ 1,605 |

**NOTE 6. Revenue**

*U.S. Government HHS BARDA Contract*

In September 2015, HHS BARDA awarded the Company a contract to support the advanced development of a more effective and universal influenza vaccine to improve seasonal and pandemic influenza preparedness. On each of May 25 and July 18, 2017, and June 28, 2018, the Company entered into a Modification of Contract with HHS BARDA, the combined effect being to increase the value of the existing $14 million contract by $1.7 million and to extend it through September 30, 2018. The modified contract is a cost-plus-fixed-fee contract, which reimburses the Company for allowable direct contract costs plus allowable indirect costs and a fixed-fee, totaling $15.7 million. The Company recognized revenue of $1,344,000 and $5,839,000 during the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, the cumulative revenue recorded from inception under the HHS BARDA contract represents the maximum amount billable under the contract as presently modified, with no further change orders envisaged.

Billings under the contract are based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. Indirect rates as well as allowable costs are subject to audit by HHS BARDA on an annual basis. Management believes that revenues recognized to date have been recorded in amounts that are expected to be realized upon final audit and settlement. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly in the period that the adjustments are known and collection is probable. Costs relating to contract acquisition are expensed as incurred. The Company does not consider any of the revenue recorded as of December 31, 2018 or 2017, to be at risk of reversal.

*Royalty agreements*

Aviragen entered into a royalty-bearing research and license agreement with GlaxoSmithKline, plc ("GSK") in 1990 for the development and commercialization of zanamivir, a neuraminidase inhibitor marketed by GSK as Relenza to treat influenza. Most of the Company's Relenza patents have expired and the only substantial remaining intellectual property related to the Relenza patent portfolio, which is solely owned by the Company and exclusively licensed to GSK, is scheduled to expire in July 2019 in Japan, at which time royalty revenue will cease. The post-Merger royalty revenue related to Relenza recognized in the year ended December 31, 2018, was $788,000, representing 7% of net sales in Japan.

The Company also generates royalty revenue from the sale of Inavir in Japan, pursuant to a collaboration and license agreement that Aviragen entered into with Daiichi Sankyo Company, Limited, or Daiichi Sankyo, in 2009. In September 2010, laninamivir octanoate was approved for sale by the Japanese Ministry of Health and Welfare for the treatment of influenza in adults and children, which Daiichi Sankyo markets as Inavir. Under the agreement, the Company currently receives a 4% royalty on net sales of Inavir in Japan and was eligible to earn sales milestone payments, including a one-off payment of $5.0 million if net sales exceeded 20 billion Yen in one year. This target was achieved in the three months ended March 31, 2018, prior to the Merger, and Aviragen recognized the related $5.0 million as royalty revenue prior to the Merger. The last patent related to Inavir is set to expire in December 2029 in Japan, at which time royalty revenue will cease. The post-Merger royalty revenue related to Inavir recognized in the year ended December 31, 2018, was $552,000. In addition, the Company recognized non-cash royalty revenue related to the sale of future royalties (see Note 7) of $1,475,000.Both the royalty revenue and the non-cash royalty revenue related to the sale of future royaltieshave been subjected to a 5% withholding tax in Japan, for which $102,000 was included in income tax expense in the year ended December 31, 2018.

**NOTE 7. Liabilities Related to Sale of Future Royalties**

In April 2016, Aviragen entered into a Royalty Interest Acquisition Agreement (the "HCRP Agreement") with HCRP. Under the Agreement, HCRP made a $20.0 million cash payment to Aviragen in consideration for acquiring certain royalty rights ("Royalty Rights") related to the approved product Inavir in the Japanese market. The Royalty Rights were obtained pursuant to the collaboration and license agreements (the "License Agreement") and a commercialization agreement that the Company entered into with Daiichi Sankyo. Per the terms of the HCRP Agreement, HCRP is entitled to the first $3.0 million plus 15% of the next $1.0 million in royalties earned in each year commencing on April 1, with any excess revenue being retained by the Company.

Under the relevant accounting guidance, due to a limit on the amount of royalties that HCRP can earn under the arrangement, this transaction was accounted for as a liability that will be amortized using the interest method over the life of the arrangement. The Company has no obligation to pay any amounts to HCRP other than to pass through to HCRP its share of royalties as they are received from Daiichi Sankyo. In order to record the amortization of the liability, the Company is required to estimate the total amount of future royalty payments to be received under the License Agreement and the payments that will be passed through to HCRP over the life of this agreement. The sum of the pass-through amounts less the net proceeds received will be recorded as non-cash interest expense over the life of the liability. Consequently, the Company imputes interest on the unamortized portion of the liability and records non-cash interest expense using an estimated effective interest rate. The Company will periodically assess the expected royalty payments, and to the extent such payments are greater or less than the initial estimate, the Company will adjust the amortization of the liability and interest rate. As a result of this accounting, even though the Company does not retain HCRP's share of the royalties, it will continue to record non-cash revenue related to those royalties until the amount of the associated liability and related interest is fully amortized.

**VAXART, INC. AND SUBSIDIARIES**

**Notes to the Consolidated Financial Statements**

The following table shows the activity within the liability account since the Merger (in thousands):

| | | |
|---|---|---|
| Total Liability related to sale of future royalties, February 13, 2018 | $ | 15,900 |
| Non-cash royalty revenue paid to HCRP | | (18) |
| Non-cash interest expense recognized | | 1,859 |
| Total Liability related to sale of future royalties, December 31, 2018 | $ | 17,741 |

**NOTE 8. Convertible Promissory Notes, Related Parties**

On December 10, 2014, the Company entered into a note purchase agreement with certain existing preferred stockholders under which the Company issued convertible promissory notes during December 2014 for total proceeds of $18.4 million.

On November 20, 2015, the Company entered into a second note purchase agreement with certain existing preferred stockholders under which the Company issued convertible promissory notes during November and December 2015 for total proceeds of $11.0 million. These notes were issued with the same terms as the notes issued in 2014.

As the holders of the convertible promissory notes each have an equity ownership in the Company, the convertible promissory notes were considered to be a related-party transaction.

The convertible promissory notes bore interest at a rate of 8.0% per annum. The principal and accrued interest on the notes were automatically convertible, upon a future issuance of convertible preferred stock having total proceeds of at least $25.0 million, into that same stock at a conversion price equal to 90% of the price paid by other investors in the financing event. Upon a liquidation event, such as an acquisition or initial public offering, at the election of the majority of the noteholders in each issuance, the principal and accrued interest on the notes could either (i) be paid in full at the initial closing of the liquidation event, or (ii) automatically convert into the Company's Series C convertible preferred stock at a conversion price based on a specified valuation.

After two years, if the notes had not been converted, the holders of a majority of the principal amount had the option to require the entire principal balance and accrued interest to become due and payable. However, in December 2016, in conjunction with the loan agreement with Oxford Finance (see note 9), all of the holders of convertible promissory notes signed subordination agreements, under which they agreed not to demand or receive any payment until all amounts owed to Oxford Finance under the loan agreement were fully paid in cash, thus extending the due dates of the promissory notes potentially to January 2021. This change reflected a debt modification that was not considered substantially significant. Accordingly, the Company did not apply extinguishment accounting, but accounted for the modification on a prospective basis.

The convertible promissory notes had redemption features that were determined to be a compound embedded derivative requiring bifurcation and separate accounting at estimated fair value. The estimated fair value of the embedded derivative upon issuance was a liability of $1.9 million for the notes issued in 2014 and $1.3 million for the notes issued in 2015. The estimated fair value of these derivative instruments was recognized as a debt discount and as an embedded derivative liability on the balance sheet upon issuance of the convertible promissory notes. The embedded derivative required periodic re-measurements to fair value while the instruments were still outstanding (see Note 4). There was no beneficial conversion feature as the conversion feature value was accounted for in the embedded derivative.

The Company estimated the fair value of the compound embedded derivative utilizing a Monte Carlo Simulation model. The inputs used to determine the estimated fair value of the embedded derivative instrument included the probability of an underlying event triggering the redemption event and its timing prior to the maturity date of the convertible promissory notes. The fair value measurement was based upon significant inputs not observable in the market, including a valuation of the Company performed by an independent third-party at each balance sheet date. By December 31, 2017, the embedded derivative had zero value because the Merger (see Note 1), which was considered 90% probable of occurring, would not have triggered redemption and, had the Merger not occurred, it was unlikely that the Company would have found an alternative source of financing on favorable terms, so there would have been zero redemption value. The embedded derivative was extinguished when the Merger occurred on February 13, 2018.

The Company incurred total debt issuance costs of $20,000 in connection with the 2014 issuance and $7,000 in connection with the 2015 issuance. The debt issuance costs, which were recorded as an additional debt discount, were being amortized over the term of the notes.

As of December 31, 2017, the balance of the convertible promissory notes was $35.3 million, comprising principal of $29.4 million plus accrued interest associated with the convertible promissory notes of $6.3 million, offset by unamortized debt discount of $0.4 million. Interest expense related to the convertible promissory notes, including amortization of debt discount, totaled $0.3 million and $2.5 million in the years ended December 31, 2018 and 2017, respectively. The charge in 2018 related to the 43 days prior to the Merger, whereas the charge in 2017 related the full year.

On February 13, 2018, the balance of the convertible promissory notes was $35.6 million, comprising accrued interest associated with the convertible promissory notes amounted to $6.6 million plus principal of $29.4 million, offset by the unamortized debt discount to $0.4 million. On that date, in conjunction with the Merger, the convertible promissory notes were exchanged for 1,571,702 shares of the Company's common stock which, based on the closing stock price of $9.05, had a value of $14.2 million. The difference of $21.4 million was recorded as a capital contribution.

**NOTE 9. Secured Promissory Note Payable to Oxford Finance**

On December 22, 2016, the Company entered into a loan and security agreement (the "Loan Agreement") with Oxford Finance, under which the Company borrowed $5.0 million. The $5.0 million loan, which bears interest at 30-day U.S. LIBOR plus 6.17%, is evidenced by a secured promissory note and is repayable over four years, with interest only payable over the first 12 months and the balance fully amortized over the subsequent 36 months. The loan is secured by substantially all the Company's assets, except for intellectual property.

In conjunction with the execution of the Loan Agreement, all the holders of convertible promissory notes signed subordination agreements, under which they agreed to subordinate in favor of Oxford Finance all amounts due under their promissory notes and any security interest in the Company's property. In addition, the holders of the notes agreed that they would not demand or receive any payment until all amounts owed to Oxford Finance under the Loan Agreement have been fully paid in cash. Upon repayment, an additional final payment equal to $325,000 is due, which is being accreted as interest expense over the term of the loan using the effective-interest method.

In connection with the Loan Agreement, the Company issued a warrant to Oxford Finance to purchase 7,563 shares of its Series C convertible preferred stock at an exercise price of $33.11 per share (the "Warrant"). The fair value of the Warrant at the date of issuance was approximately $134,000, which was recorded as debt discount and is being amortized as interest expense over the term of the loan using the effective-interest method. The annual effective interest rate of the note, including the accretion of the final payment and the amortization of the debt discount, is approximately 10.5%. The Company recorded interest expense related to the Loan Agreement of $469,000 and $518,000 during the years ended December 31, 2018 and 2017, respectively, of which $356,000 and $335,000 was paid, respectively.

The Warrant provided that if the share price at the next equity financing was less than the Warrant exercise price, then the Warrant would be for the new class of shares, the exercise price would be the new class share price, and the number of shares would be calculated by dividing $250,000 by the new class share price. Due to this anti-dilution protection, the Company determined that the Warrant needed to be recorded as a liability, and therefore estimated the fair value of the Warrant upon issuance and at each balance sheet date, with any changes in the fair value being recorded within (loss) gain on revaluation of financial instruments, net in other income and (expenses) in the statements of operations and comprehensive loss.

Due to the antidilution protection, following the Merger, the Warrant was amended to allow the holder to purchase 10,914 shares of common stock at an exercise price of $22.99 per share. Since the amended Warrant contains no non-standard antidilution protections or similar features, the fair value of approximately $70,000 on February 13, 2018, was reclassified to equity.

VAXART, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

**NOTE 10. Commitments and Contingencies**

***(a) Leases***

The Company has four office and research and development facilities in South San Francisco, California, under noncancelable operating leases. The principal lease, for office and research and development premises, expires on April 30, 2020, subject to the Company's option to extend the lease at the then market rate for an additional five-year period. The remaining three leases all expire on August 31, 2019. In addition, as a result of the Merger, the Company also leases office space in Alpharetta, Georgia, under a lease expiring on February 28, 2021, which, commencing in November 2018, the Company has subleased for the remainder of the lease term for less than it is required to pay under the head lease and accordingly it recorded a lease loss charge of $253,000 on the cease-use date in the three months ending December 31, 2018, which, along with the related impairment of property and equipment (see Note 5), was recorded as a component of costs of exit from leased premises within operating expenses.

Liabilities related to costs of exit from leased premises are summarized as follows (in thousands):

| | | |
|---|---|---|
| Balance as of January 1, 2018 | $ | — |
| Costs of exit from leased premises | | 359 |
| Deferred rent on cease-use date | | 19 |
| Impairment of property and equipment | | (106) |
| Cash paid, net of receipts | | (41) |
| Accretion charges, included in rent expense | | 2 |
| Balance as of December 31, 2018 | $ | 233 |

Rent expense is recognized on a straight-line basis over the noncancelable term of each operating lease and, accordingly, the Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability, which is included within accrued expenses. Rent expense was $875,000 and $564,000 for the years ended December 31, 2018 and 2017, respectively. Under the terms of the lease agreements, the Company is also responsible for certain insurance, property tax and maintenance expenses. The Company also leases equipment under three operating leases that expire between May and September 2019.

Future minimum payments and sublease income under operating leases as of December 31, 2018, are as follows:

| Years Ending December 31, | Lease Payments | Sublease Income |
|---|---|---|
| | (in thousands) | |
| 2019 | $ 859 | $ 213 |
| 2020 | 411 | 219 |
| 2021 | 56 | 38 |
| Thereafter | — | — |
| Total | $ 1,326 | $ 470 |

***(b) Indemnifications***

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend indemnified parties for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors' and officers' insurance.

VAXART, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

***(c) Litigation***

From time to time the Company may be involved in claims arising in connection with its business. Based on information currently available, the Company believes that the amount, or range, of reasonably possible losses in connection with any pending actions against it in excess of established reserves, in the aggregate, not to be material to its consolidated financial condition or cash flows. However, losses may be material to the Company's operating results for any particular future period, depending on the level of income or loss for such period.

**NOTE 11. Stockholders' Equity**

***(a) Convertible Preferred Stock***

The Company is authorized to issue 5,000,000 shares of preferred stock, $0.10 par value per share. The Company's board of directors may, without further action by the stockholders, fix the rights, preferences, privileges and restrictions of up to an aggregate of 5,000,000 shares of preferred stock in one or more series and authorize their issuance. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of our common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deterring or preventing a change of control or other corporate action. No shares of preferred stock are currently outstanding, and the Company has no present plan to issue any shares of preferred stock.

All of Private Vaxart's convertible preferred stock was converted into common stock on February 13, 2018, in conjunction with the Merger.

As of December 31, 2017, convertible preferred stock consisted of the following:

| | Shares authorized | Shares outstanding | Net carrying value | Liquidation preference |
|---|---|---|---|---|
| | | | (in thousands) | (in thousands) |
| Series A | 94,988 | 94,988 | $ 2,949 | $ 2,737 |
| Series B | 747,095 | 520,973 | 16,115 | 17,219 |
| Series C | 820,088 | 605,103 | 19,877 | 20,000 |
| Total | 1,662,171 | 1,221,064 | $ 38,941 | $ 39,956 |

Significant provisions of the convertible preferred stock were as follows:

*Dividends* – The holders of Series C convertible preferred stock were entitled to receive non-compounding cumulative dividends, in preference to any dividends payable to holders of Series B and Series A convertible preferred stock or common stock, at an annual dividend rate of $2.64416 per share, as adjusted for any stock splits, stock dividends, recapitalizations, or the like. Such cumulative dividends were payable within ten days of demand of the holders of at least a majority of the then outstanding Series C convertible preferred stock, or automatically upon a liquidation event. Dividends accumulated from the date of issuance and were payable, whether or not declared, before any dividend on Series B and Series A convertible preferred stock or common stock could be paid or declared. Series C convertible preferred stock shares issued as stock dividends were not entitled to cumulative dividends. The holders of Series C convertible preferred stock could elect whether the cumulative dividends would be paid in cash or in shares of Series C convertible preferred stock based on the original issue price of Series C convertible preferred stock of $33.05196 per share. In the event the board of directors declared a cash dividend in addition to the above cumulative dividends (a Special Dividend), the holders of Series C convertible preferred stock would have been entitled to receive, in preference to any dividends payable to the holders of Series B and Series A convertible preferred stock or common stock, a per share amount equal to the sum of: (a) the original issue price of Series C convertible preferred stock, and (b) all accrued and/or declared but unpaid dividends on such Series C convertible preferred stock, including the cumulative dividends. No dividends were declared during any of the periods presented. As of February 13, 2018, when the convertible preferred stock was converted into common stock, and December 31, 2017, accumulated and undeclared dividends for Series C convertible preferred stock were $7.3 million and $7.1 million, respectively ($12.06 per share and $11.74 per share, respectively, of the outstanding Series C convertible preferred stock). On February 13, 2018, in conjunction with the Merger, the Series C convertible preferred stock and the related accumulated dividends were converted into 696,028 and 253,851 shares of common stock, respectively.

**VAXART, INC. AND SUBSIDIARIES**

**Notes to the Consolidated Financial Statements**

The holders of Series B convertible preferred stock were entitled to receive non-compounding cumulative dividends, in preference to any dividends payable to holders of Series A convertible preferred stock or common stock, at the annual dividend rate of $2.64416 per share, as adjusted for any stock splits, stock dividends, recapitalizations, or the like. Such cumulative dividends were payable within ten days of demand of the holders of at least a majority of the then outstanding Series B convertible preferred stock or automatically upon a liquidation event. Dividends accumulated from the date of issuance and were payable, whether or not declared, before any dividend on Series A convertible preferred stock or common stock could be paid or declared. Series B convertible preferred shares issued as stock dividends were not entitled to cumulative dividends. The holders of Series B convertible preferred stock could elect whether the cumulative dividends would be paid in cash or in shares of Series B convertible preferred stock based on the original issue price of Series B convertible preferred stock of $33.05196 per share. In the event the board of directors declared a cash dividend in addition to the above cumulative dividends (a Special Dividend), the holders of Series B convertible preferred stock would have been entitled to receive, in preference to any dividends payable to the holders of Series A convertible preferred stock or common stock, a per share amount equal to the sum of: (a) the original issue price of Series B convertible preferred stock, and (b) all accrued and/or declared but unpaid dividends on such Series B convertible preferred stock, including the cumulative dividends. No dividends were declared during any of the periods presented. As of February 13, 2018, when the convertible preferred stock was converted into common stock, and December 31, 2017, accumulated and undeclared dividends for Series B convertible preferred stock were $7.6 million and $7.5 million, respectively ($15.78 per share and $15.46 per share, respectively, of the 483,387 shares of outstanding Series B convertible preferred stock on which dividends accrued). On February 13, 2018, in conjunction with the Merger, the Series B convertible preferred stock and the related accumulated dividends were converted into 599,259 and 265,340 shares of common stock, respectively.

The holders of Series A convertible preferred stock were entitled to receive noncumulative dividends, in preference to any dividends payable to holders of common stock, at the annual dividend rate of $2.30449 per share, as adjusted for any stock splits, stock dividends, recapitalizations, or the like, if declared by the board of directors. On February 13, 2018, in conjunction with the Merger, the Series A convertible preferred stock was converted into 104,065 shares of common stock.

*Conversion* – At the option of the holder, each share of convertible preferred stock was convertible, one-for-one, subject to adjustment for anti-dilution protection, into shares of common stock. Each share automatically converted into the number of shares of common stock into which the shares were convertible at the then applicable conversion ratio upon: (1) the closing of the sale of the Company's common stock in a public offering provided the offering price per share was not less than three times the Series C convertible preferred stock original issue price of $33.05196 and the aggregate gross proceeds were not less than $30.0 million, or (2) upon receipt of a written consent of the holders of a majority of the then outstanding shares of convertible preferred stock voting as a single class on an as-converted basis.

*Liquidation* – In the event of any liquidation, dissolution or winding up of the Company, including a merger or acquisition where the beneficial owners of the Company's common and convertible preferred stock owned less than 50% of the surviving entity, or a sale of all or substantially all assets, the holders of Series C convertible preferred stock would have been entitled to receive a per share amount equal to $33.05196 (subject to adjustment for stock splits, stock dividends, recapitalizations, or the like), plus all dividends accrued, payable and/or in arrears (whether or not declared) minus the amount of any Special Dividends previously paid. After payment of the full liquidation preference of Series C convertible preferred stock, the holders of Series B convertible preferred stock would have been entitled to receive a per share amount equal to $33.05196 (subject to adjustment for stock splits, stock dividends, recapitalizations, or the like), plus all dividends accrued, payable and/or in arrears (whether or not declared) minus the amount of any Special Dividends previously paid. After payment of the full liquidation preference of Series B convertible preferred stock, the holders of Series A convertible preferred stock would have been entitled to receive an amount equal to $28.80613 per share, as adjusted, plus all declared but unpaid dividends prior and in preference to any distribution to the holders of common stock. In each case, if the proceeds of such an event were insufficient to permit the liquidation payment to a particular class, any proceeds legally available for distribution to that class would have been distributed ratably among the holders of that class in proportion to the preferential amounts that each holder was entitled to receive. Following payment of all convertible preferred stock preferences, any remaining legally available assets of the Company would have been distributed to the holders of common stock and convertible preferred stock pro rata, based on the greatest number of shares of common stock held on an as-converted basis.

**VAXART, INC. AND SUBSIDIARIES**

**Notes to the Consolidated Financial Statements**

*Voting* – The holders of convertible preferred stock were entitled to the number of votes equal to the number of shares of common stock into which each share of Series A, Series B, and Series C convertible preferred stock could have been converted on the record date for the vote or consent of the stockholders, except as otherwise required by law, and had voting rights and powers equal to the voting rights and powers of the common stockholders. The holders of Series A convertible preferred stock, voting as a separate class, were entitled to elect one member of the board of directors. As long as a specified investor held at least one share of Series C convertible preferred stock, the specified investor was able to designate one member of the board of directors, who would have been elected by the holders of Series C convertible preferred stock voting as a separate class. As long as a specified investor held least one share of Series B convertible preferred stock, the specified investor was able to designate one member of the board of directors, who would have been elected by the holders of Series B convertible preferred stock voting as a separate class. The holders of common stock, voting as a separate class, were entitled to elect two members of the board of directors, one of whom was the duly appointed chief executive officer of the Company.

*Protective Provisions* – So long as at least 20,134 shares of Series C convertible preferred stock remained outstanding and for so long as at least 20,134 shares of Series B convertible preferred stock remained outstanding, Series C holders and Series B holders, voting as a single class on an as-converted basis, needed to approve certain specified corporate actions such as amending the certificate of incorporation, authorizing additional shares of stock or additional directors, redeeming stock and entering into certain strategic relationships.

*Redemption* – The convertible preferred stock was not redeemable. There were no liquidation events under the control of preferred stockholders that could have resulted in liquidation in which only the preferred stockholders would have participated. Accordingly, the convertible preferred stock was classified within stockholders' equity (deficit) on the Company's consolidated balance sheets.

***(b) Common Stock***

Except as otherwise required by law or as otherwise provided in any certificate of designation for any series of preferred stock, the holders of common stock possess all voting power for the election of the Company's directors and all other matters requiring stockholder action. Holders of common stock are entitled to one vote per share on matters to be voted on by stockholders. Holders of common stock are entitled to receive such dividends, if any, as may be declared from time to time by the Company's board of directors in its discretion out of funds legally available therefore. In no event will any stock dividends or stock splits or combinations of stock be declared or made on common stock unless the shares of common stock at the time outstanding are treated equally and identically. As of December 31, 2018, no dividends had been declared by the board of directors.

In the event of the Company's voluntary or involuntary liquidation, dissolution, distribution of assets or winding-up, the holders of the common stock will be entitled to receive an equal amount per share of all of the Company's assets of whatever kind available for distribution to stockholders, after the rights of the holders of the preferred stock have been satisfied. There are no sinking fund provisions applicable to the common stock.

The Company had shares of common stock reserved for issuance as follows:

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| Convertible preferred stock outstanding | — | 1,221,064 |
| Options issued and outstanding | 865,163 | 304,850 |
| Available for future grants of equity awards | 223,377 | — |
| Cumulative convertible preferred stock dividends | — | 441,096 |
| Common stock warrants | 10,914 | 10,914 |
| Total | 1,099,454 | 1,977,924 |

VAXART, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

**NOTE 12. Equity Incentive Plans**

Prior to the Merger, the Company issued equity awards for compensation purposes to employees, directors and consultants under the Company's 2007 Equity Incentive Plan (the "2007 Plan"). The 2007 Plan expired in July 2017, since when the Company has had no shares of common stock available for issuance under the 2007 Plan since awards under the 2007 Plan no longer become available for future issuance if such awards are forfeited or otherwise terminate. Each outstanding stock option to acquire shares of Private Vaxart stock, whether vested or unvested, was assumed in the Merger after adjustment for the impact of the Conversion and the Reverse Stock Split.

In November 2016, Aviragen's stockholders approved the 2016 Equity Incentive Plan ("2016 Equity Plan"), under which all outstanding awards under their previous plans became available for issuance under the 2016 Equity Plan if such awards are forfeited or otherwise terminate. The purpose of the 2016 Equity Plan is to assist the Company in attracting and retaining valued employees, consultants and non-employee directors by offering them a greater stake in the Company's success and a closer identity with it, and to encourage ownership of the Company's shares by such persons.

Under the 2016 Equity Plan, the Company is authorized to issue incentive stock options ("ISOs"), non-qualified stock options ("NQSOs"), restricted stock ("RSAs") and restricted stock units ("RSUs"). Awards that expire or are canceled generally become available for issuance again under the 2016 Equity Plan. All awards outstanding, along with the number of shares of the Company's common stock available under the 2016 Equity Plan, were adjusted for the impact of the Reverse Stock Split and remain subject to adjustment in the event of a stock split, stock dividend or other extraordinary dividend, or other similar change in the Company's common stock or capital structure. Awards may vest over varying periods, as specified by the Company's Board of Directors for each grant, and have a maximum term of ten years from the grant date.

A summary of stock option transactions in each of the two years ended December 31, 2018, is as follows:

| | Shares Available For Grant | Number of Options Outstanding | Weighted Average Exercise Price |
|---|---|---|---|
| Balance at January 1, 2017 | 99,644 | 275,539 | $ 11.32 |
| Granted | (78,406) | 78,406 | $ 4.07 |
| Exercised | — | (2,834) | $ 8.58 |
| Forfeited | 33,012 | (33,012) | $ 11.49 |
| Canceled | 13,249 | (13,249) | $ 12.00 |
| Termination of Plan | (67,499) | — | $ — |
| Balance at December 31, 2017 | — | 304,850 | $ 9.50 |
| Assumed on consummation of Merger | 291,102 | 627,106 | $ 26.33 |
| Granted | (431,100) | 431,100 | $ 5.17 |
| Exercised | — | (2,013) | $ 6.49 |
| Forfeited | 71,500 | (89,903) | $ 5.90 |
| Canceled | 269,148 | (405,977) | $ 34.64 |
| Balance at December 31, 2018 | 200,650 | 865,163 | $ 8.13 |

In addition, the 2016 Equity Plan has a reserve of 22,727 shares available for future issuance as RSAs and RSUs. As of December 31, 2018, no such awards have been granted under the 2016 Equity Plan.

As of December 31, 2018, there were 865,163 options outstanding with a weighted average exercise price of $8.13, a weighted average remaining term of 6.14 years and zero aggregate intrinsic value. Of these options, 452,905 were vested, with a weighted average exercise price of $10.58, a weighted average remaining term of 3.35 years and zero aggregate intrinsic value.

The aggregate intrinsic value represents the total pre-tax value (i.e., the difference between the Company's stock price and the exercise price) of stock options outstanding as of December 31, 2018, based on our common stock closing price of $1.88, which would have been received by the option holders had all their in-the-money options been exercised as of that date.

The grant date fair value of options vested in the years ended December 31, 2018 and 2017, was $332,000 and $533,000, respectively. The intrinsic value of options exercised in the years ended December 31, 2018 and 2017, was zero and $1,000, respectively.

The weighted average grant date fair value of options awarded in the years ended December 31, 2018 and 2017, was $3.59 and $2.99, respectively. Fair values were estimated using the following assumptions:

| | Year Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| Risk-free interest rate | 2.80% | 1.87% |
| Expected term | 5.96 Years | 6.09 Years |
| Expected volatility | 79% | 91% |
| Dividend yield | 0% | 0% |

Total stock-based compensation recognized for options was as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| | (in thousands) | |
| Research and development | $ 254 | $ 262 |
| General and administrative | 285 | 215 |
| Total stock-based compensation | $ 539 | $ 477 |

As of December 31, 2018, the unrecognized stock-based compensation cost related to outstanding stock options that are expected to vest was $1.1 million, which the Company expects to recognize over an estimated weighted average period of 2.75 years.

**NOTE 13. Income Taxes**

The provision for income taxes consists of the following for the years ended December 31, 2018 and 2017:

| | Year Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| | (In thousands) | |
| Current: | | |
| Federal | $ — | $ — |
| State | 3 | — |
| Foreign | 106 | — |
| Total Current | $ 109 | $ — |
| Deferred: | | |
| Federal | $ — | $ — |
| State | — | — |
| Foreign | — | — |
| Total Deferred | $ — | $ — |
| Provision for income taxes | $ 109 | $ — |

VAXART, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

The components of the deferred tax assets as of December 31, 2018 and 2017, are as follows:

| | December 31, 2018 | December 31, 2017 |
|---|---|---|
| Deferred tax assets: | (In thousands) | |
| Net operating loss carry-forwards | $ 43,822 | $ 19,441 |
| Research and development tax credits | 3,357 | 2,979 |
| Capitalized research and development | 2,326 | — |
| Sale of future royalties | 8,383 | — |
| Accruals, reserves and other | 714 | 544 |
| Total deferred tax assets | 58,602 | 22,964 |
| Valuation allowance | (48,626) | (22,964) |
| Deferred tax assets net of valuation allowance | 9,976 | — |
| Deferred tax liabilities: | | |
| Intangible assets | (9,976) | — |
| Total deferred tax liabilities | (9,976) | — |
| Net deferred tax assets | $ — | $ — |

A reconciliation of the provision for income taxes with the expected provision for income taxes computed by applying the federal statutory income tax rate of 21% and 34% to the net loss before provision for income taxes for the years ended December 31, 2018 and 2017, respectively:

| | Year Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| U.S. federal taxes at statutory rate | 21.0 % | 34.0 % |
| State taxes (net of federal benefit) | 0.6 | 14.2 |
| Foreign rate differential | 3.1 | — |
| Global intangible low-taxed income | (8.8) | — |
| Permanent items: | | |
| Convertible note interest | (0.4) | (10.8) |
| Revaluation of derivative liabilities | — | 11.9 |
| Others | (2.1) | (1.4) |
| Tax credits | 2.1 | 8.0 |
| Change in valuation allowance | (20.4) | 43.4 |
| Impact of tax reform rate change | — | (97.0) |
| NOL and credit adjustments | (3.8) | (2.4) |
| Bargain purchase gain | 8.1 | — |
| Other | — | 0.1 |
| Provision for income taxes | (0.6)% | — % |

The Company's actual tax expense differed from the statutory federal income tax expense using a tax rate of 21% for the year ended December 31, 2018, primarily due to, state and foreign income taxes, nondeductible expenses, research and development tax credits, and the change in valuation allowance. The Company's actual tax expense differed from the statutory federal income tax expense using a tax rate of 21% for the year ended December 31, 2017, primarily due to remeasurement of deferred taxes due to change in federal tax rate under the Tax Cuts and Jobs Act (the "TCJA"), state income taxes, nondeductible expenses, research and development tax credits, and the change in valuation allowance.

On December 22, 2017, the TCJA was signed into law. The TCJA decreased the U.S. corporate federal income tax rate from 35% to 21% effective January 1, 2018. The TCJA also includes a number of other provisions including the elimination of loss carrybacks and limitations on the use of future losses, repeal of the Alternative Minimum Tax regime, and the introduction of a base erosion, anti-abuse tax and 100% expense allowance for certain properties. These provisions are not expected to have immediate effect on the Company.

**VAXART, INC. AND SUBSIDIARIES**

**Notes to the Consolidated Financial Statements**

The key impact of the TCJA on the Company's financial statements was the re-measurement of the deferred tax balances to the new corporate tax rate in the year ended December 31, 2017. U.S. GAAP requires the re-measurement of the Company's deferred tax balances as of the enactment date of the TCJA, based on the rates at which the balances are expected to reverse in the future. The TCJA reduced the corporate tax rate to 21%, effective January 1, 2018. The Company recorded a decrease in its deferred tax assets of $4.2 million with a corresponding reduction to its valuation allowance of $4.2 million for the year ending December 31, 2017, primarily related to the impact of the TCJA.

As of December 31, 2018 and 2017, the Company had a net operating loss ("NOL") carryforwards of $92.3 million and $69.5 million for federal purposes, and $76.9 million and $75.0 million for state purposes, respectively. If not utilized, these carryforwards will begin to expire in 2024 for federal, and 2028 for state purposes.

As of December 31, 2018, the Company also has accumulated tax losses of $14.4 million for Australia, $24.7 million for the United Kingdom and $37.7 million for France available for carry forward against future earnings, which under relevant tax laws do not expire but may not be available under certain circumstances. As of December 31, 2018, the Company's foreign subsidiaries have no positive accumulated earnings. As such, no federal or state income taxes have been provided on the losses of its foreign subsidiaries. If in the future there are positive earnings generated from the Company's foreign subsidiaries, the Company will evaluate whether to record any applicable federal and state income taxes on such earnings.

As of December 31, 2018 and 2017, the Company had federal research and development tax credit carryforwards of $3.0 million and $2.7 million, respectively and state research and development tax credit carryforwards of $2.3 million and $2.0 million, respectively, before offset for unrecognized tax benefits, to offset future income tax liabilities. The federal research and development tax credits will start to expire in 2027, if not utilized, while the state research and development tax credit can be carried forward indefinitely.

Sections 382 and 383 of the Internal Revenue Code provides for a limitation on the annual use of NOL and research and development tax credit carryforwards following certain ownership changes that could limit the Company's ability to utilize these carryforwards. The Company's losses and credit carryforwards may be subject to these limitations. The Company has not performed an analysis to determine if such ownership changes have occurred. An analysis will be performed prior to recognizing the benefits of any losses or credits in the financial statements.

The Company is required to reduce its deferred tax assets by a valuation allowance if it is more likely than not that some or all of its deferred tax assets will not be realized. Management must use judgment in assessing the potential need for a valuation allowance, which requires an evaluation of both negative and positive evidence. The weight given to the potential effect of negative and positive evidence should be commensurate with the extent to which it can be objectively verified. In determining the need for and amount of the valuation allowance, if any, the Company assesses the likelihood that it will be able to recover its deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical cumulative losses, the Company determined that, based on all available evidence, there was substantial uncertainty as to whether it will recover recorded net deferred taxes in future periods. Accordingly, the Company recorded a valuation allowance against all of its net deferred tax assets as of December 31, 2018 and 2017. The net change in total valuation allowance was an increase of approximately $25.7 million for the year ended December 31, 2018

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| | (in thousands) | |
| Beginning Balance | $ 1,404 | $ 1,231 |
| Additions based on tax positions related to the current year | 181 | 173 |
| Decreases related to prior years' tax positions | (3) | — |
| Ending Balance | $ 1,582 | $ 1,404 |

The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. During the year ended December 31, 2017 and 2018, the Company recognized no interest and penalties associated with unrecognized tax benefits. There are no tax positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within twelve months of the reporting date.

VAXART, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

The Company files income tax returns in the U.S, Australia, France and the United Kingdom, as well as with various U.S. states. The Company is subject to tax audits in all jurisdictions in which it files income tax returns. Tax audits by their very nature are often complex and can require several years to complete. There are currently no tax audits that have commenced with respect to income tax returns in any jurisdiction.

Under the tax statute of limitations applicable to the Internal Revenue Code, the Company and its U.S. subsidiary, either standalone or as part of the consolidated group, is no longer subject to U.S. federal income tax examinations by the Internal Revenue Service for tax years before tax year 2016. Under the statute of limitations applicable to most state income tax laws, the Company is no longer subject to state income tax examinations by tax authorities for tax years before 2015 in states in which it has filed income tax returns. However, because the Company is carrying forward income tax attributes, such as net operating losses and tax credits from 2004 and earlier tax years, these attributes can still be audited when utilized on returns filed in the future. The Company is subject to foreign tax examinations by tax authorities for fiscal year 2014 and forward.

**NOTE 14. Net Loss Per Share Attributable to Common Stockholders**

The following table presents the calculation of basic and diluted net loss per share (in thousands, except share and per share amounts):

| | Year Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| Net loss | $ (18,007) | $ (9,582) |
| Series B and C preferred dividend | (339) | (2,878) |
| Net loss attributable to common stockholders | $ (18,346) | $ (12,460) |
| Shares used to compute net loss per share, basic and diluted | 6,316,065 | 135,953 |
| Net loss per share attributable to common stockholders, basic and diluted | $ (2.90) | $ (91.65) |

No adjustment has been made to the net loss attributable to common stockholders as the effect would be anti-dilutive due to the net loss.

The following potentially dilutive securities were excluded from the computation of diluted weighted average shares outstanding because they would have been antidilutive:

| | Year Ended December 31, | |
|---|---|---|
| | 2018 | 2017 |
| Options to purchase common stock | 839,396 | 295,243 |
| Warrant to purchase common stock | 9,658 | — |
| Warrant to purchase convertible preferred stock | 891 | 7,563 |
| Series B and C convertible preferred stock outstanding, including cumulative dividends | 213,760 | 1,567,172 |
| Series A convertible preferred stock outstanding | 12,260 | 94,988 |
| Convertible promissory notes, related party (as converted) | 185,159 | 754,289 |
| Total potentially dilutive securities excluded from denominator of the diluted earnings per share computation | 1,261,124 | 2,719,255 |

VAXART, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

**NOTE 15. Quarterly Financial Data (Unaudited)**

Selected summarized quarterly financial information for fiscal 2018 and 2017 is as follows:

| | Year Ended December 31, 2018 | | | |
|---|---|---|---|---|
| | First | Second | Third | Fourth |
| Revenue | $ 1,503 | $ 608 | $ 281 | $ 1,767 |
| Operating expenses | $ 5,418 | $ 8,383 | $ 6,161 | $ 5,953 |
| Net income (loss) | $ 2,314 | $ (8,871) | $ (6,548) | $ (4,902) |
| Net income (loss) attributable to common stockholders | $ 1,975 | $ (8,871) | $ (6,548) | $ (4,902) |
| Net income (loss) per share – basic | $ 0.54 | $ (1.24) | $ (0.92) | $ (0.69) |
| Net income (loss) per share – diluted | $ 0.49 | $ (1.24) | $ (0.92) | $ (0.69) |

| | Year Ended December 31, 2017 | | | |
|---|---|---|---|---|
| | First | Second | Third | Fourth |
| Revenue | $ 2,310 | $ 1,854 | $ 915 | $ 760 |
| Operating expenses | $ 4,557 | $ 4,977 | $ 2,871 | $ 3,449 |
| Net loss | $ (2,796) | $ (3,538) | $ (2,173) | $ (1,075) |
| Net loss attributable to common stockholders | $ (3,506) | $ (4,256) | $ (2,898) | $ (1,800) |
| Net loss per share – basic and diluted | $ (25.84) | $ (31.37) | $ (21.36) | $ (13.16) |

**Item 9. Changes In and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

**Item 9A. Controls and Procedures**

As of the end of the period covered by this Annual Report, management performed, with the participation of our President and Chief Executive Officer (who serves as our principal executive officer and principal financial officer), an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Exchange Act rules 13a-15(e) and 15(d)-15e)). Based on such evaluation, our management concluded that as of December 31, 2018, our disclosure controls and procedures were not effective at a reasonable assurance level as a result of the material weakness described below.

**Material Weakness**

We identified the following material weakness in our internal control over financial reporting as of December 31, 2018:

> We lacked consistent processes to appropriately perform effective and timely review of account reconciliations and non-routine transactions. Therefore, there was a risk that a potential material misstatement of the financial statements would occur without being prevented or detected on a timely basis.

We have taken certain steps to remediate this material weakness, including increasing the depth and experience within our accounting and finance organization and designing and implementing improved processes and internal controls. However, our efforts to remediate this material weakness may not be effective or prevent any future material weakness or significant deficiency in our internal control over financial reporting. If our efforts are not successful, or other material weaknesses or control deficiencies occur in the future, we may be unable to report our financial results accurately on a timely basis, which could cause our reported financial results to be materially misstated and result in the loss of investor confidence and cause the market price of our common stock to decline.

**Management's Report on Internal Control Over Financial Reporting**

Management has conducted, with the participation of our President and Chief Executive Officer (who serves as our principal executive officer and principal financial officer), an assessment, including testing of the effectiveness, of our internal control over financial reporting as of December 31, 2018. Management's assessment of internal control over financial reporting was conducted using the criteria of the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control – Integrated Framework (2013),* while utilizing the additional guidance contained in COSO's *Internal Control over Financial Reporting – Guidance for Smaller Public Companies*. Based on that assessment, due to the material weakness described above, our management concluded that our internal control over financial reporting was not effective as of December 31, 2018.

**Attestation Report of Registered Public Accounting Firm**

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting pursuant to SEC rules that permit us to provide only management's report in this Annual Report.

**Changes in Internal Control over Financial Reporting**

During 2018, we hired a full-time Corporate Controller and a full-time Associate Director of SEC Reporting, both Certified Public Accountants with active licenses. We have implemented procedures in our finance department including- formal approval procedures for all journal entries and account reconciliations, and increased management oversight of financial reporting. This was done to address a material weakness relating to our lack of sufficient qualified resources and adequate processes to appropriately segregate duties and perform effective and timely review of account reconciliations and non-routine transactions that was originally identified in the audit of our financial statements for the year ended December 31, 2015 and was previously reported in Item 4 in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018. While we believe these procedures will be effective in remediating the material weakness, they were not yet fully operational as of December 31, 2018.

**Inherent Limitations on Effectiveness of Controls**

Our management, including our President and Chief Executive Officer, does not expect that our disclosure controls and procedures or our internal controls, will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Vaxart have been detected.

**Item 9B. Other Information**

None.

# PART III

## Item 10. Directors, Executive Officers and Corporate Governance

Set forth below is certain information regarding our directors and executive officers as of February 1, 2019:

| Name | Age | Position |
|---|---|---|
| ***Executive Officers*** | | |
| Wouter W. Latour, M.D. | 61 | President, Chief Executive Officer and Director |
| Sean N. Tucker, Ph.D. | 51 | Chief Scientific Officer |
| ***Directors*** | | |
| Geoffrey F. Cox, Ph.D. | 75 | Director |
| Michael J. Finney, Ph.D. | 60 | Director |
| Richard J. Markham | 68 | Chairman of the Board |
| John P. Richard | 61 | Director |
| Anne M. VanLent | 70 | Director |

Our board of directors is composed of six members all of whom were previously elected by our stockholders. All of our directors have one-year terms and stand for election annually. Vacancies on the board of directors may be filled only by persons elected by a majority of the remaining directors. A director elected by the board of directors to fill a vacancy in a class, including vacancies created by an increase in the number of directors, shall serve for the remainder of the full term and until the director's successor is duly elected and qualified.

### Executive Officers

***Wouter W. Latour, M.D.*** has served as our President and Chief Executive Officer and as a member of our board of directors since February 2018. Dr. Latour previously served as the President and Chief Executive Officer of Private Vaxart since September 2011 and served as a member of Private Vaxart's board of directors since October 2011. From June 2011 to September 2011, Dr. Latour served as Private Vaxart's Chief Operating Officer. From June 2009 until joining Vaxart, Dr. Latour was an independent consultant to life sciences companies. From January 2005 to May 2009, Dr. Latour was Chief Executive Officer and a member of the board of directors of Trinity Biosystems, Inc., a biopharmaceutical company. Prior to these roles, Dr. Latour held numerous executive positions at various pharmaceutical and biotechnology companies. Dr. Latour received an M.D. from the University of Amsterdam and an M.B.A. from Stanford University.

We believe Dr. Latour is qualified to serve on the board of directors because of his extensive experience within the life sciences industry and because of the perspective and background that he brings as Vaxart's President, Chief Executive Officer and Director.

***Sean N. Tucker, Ph.D.*** has served as our Chief Scientific Officer since February 2018 and previously served as Private Vaxart's Chief Scientific Officer since February 2010 and as a member of the Private Vaxart board of directors from March 2004 to February 2018. From March 2004 to February 2010, Dr. Tucker served as Private Vaxart's Vice President of Research and Director of Immunology. Prior to these roles, Dr. Tucker held numerous scientific and engineering roles at various biotechnology companies. Dr. Tucker received a B.S. in chemical engineering from the University of Washington, an M.S. in chemical engineering from the University of California, Berkeley and a Ph.D. in immunology from the University of Washington.

### Directors

***Geoffrey F. Cox, Ph.D.*** has served as a member of the board of directors since 2000. He was a director (2000-2012) and the Non-Executive Chairman (2007 to 2012) of Nabi Biopharmaceuticals, Inc. prior to its merger with Biota Pharmaceuticals, Inc. (subsequently Aviragen) in 2012 and then with Vaxart in 2018. He served as the interim Chief Executive Officer of QLT Inc., an ophthalmology company based in Vancouver, BC, (from October 23, 2014 to November 30, 2016) and a director (from 2012 to August 2017). Dr. Cox has extensive pharmaceutical and biotechnology experience holding a broad range of senior management and board positions with private and public companies. Dr. Cox remains the Principal of Beacon Street Advisors LLC (since 2013) which provides corporate, operational and organizational strategic advice and interim management support to life sciences companies. Previously, he was a partner with Red Sky Partners LLC, a life sciences consulting firm (from 2011 to 2013). He also served as a director of Gallus Biopharmaceuticals LLC (2011 – 2014), a biologics contract manufacturing and development company, Immunomedics, Inc., a development stage oncology company (January 2017 – March 2017) and currently serves as a director of Lakewood-Amedex LLC (since 2013), a company developing novel antibiotics and RNA silencing technology. He is also cofounder of Actu8 Immunotherapeutics Ltd., a development stage immuno-oncology technology company. Dr. Cox was Chairman, President and Chief Executive Officer of GTC Biotherapeutics Inc. (2001 to 2010), a company focused on the development of recombinant therapeutic proteins, including proteins for the treatment of rare diseases, using transgenic animal production technology. Prior to 2001, Dr. Cox was Executive Vice President, Operations of Genzyme Corporation and later Chairman, President and Chief Executive Officer of Aronex Pharmaceuticals Inc. Dr. Cox is a past Chairman of the Board of the Massachusetts Biotechnology Council. He previously served on the Board of Biotechnology Industries Association and as a member of its Health Governing and Emerging Companies Sections. Dr. Cox received a B.Sc. (Hons) in biochemistry from the University of Birmingham, U.K. and a Ph.D. in biochemistry from the University of East Anglia, U.K.

We believe Dr. Cox is qualified to serve on the board because of his extensive biotechnology industry expertise, including his many years of experience as an executive officer and board member of publicly-traded biotechnology companies.

***Michael J. Finney, Ph.D.*** has served as a member of our board of directors since February 2018 and previously served as a member of Private Vaxart's board of directors since 2007. Since October 2004, Dr. Finney has served as the Managing Director of Finney Capital, an investment firm. Since 1986, Dr. Finney has served as a founder, director and/or investor in various life sciences companies. Currently, he sits on six private company boards. From 2009 to 2011, Dr. Finney served as Vaxart's Chief Executive Officer. Dr. Finney received an A.B. in biochemical sciences from Harvard University and a Ph.D. in biology (genetics) from the Massachusetts Institute of Technology.

We believe Dr. Finney is qualified to serve on the board of directors because of his extensive experience within the life sciences industry, including as a venture capitalist.

***Richard J. Markham*** has served as a member of our board of directors since February 2018 and previously served as a member of Private Vaxart's board of directors since 2009. From November 2004 to December 2018, Mr. Markham was a partner at Care Capital, LLC, a venture capital firm. From May 2002 to August 2004, he was the Vice Chairman of the Management Board and Chief Operating Officer of Aventis SA, a pharmaceutical company. From December 1999 to May 2002, he was the Chief Executive Officer of Aventis Pharma AG, a pharmaceutical company. Previously he was the Chief Executive Officer of Hoechst Marion Roussel Inc., a pharmaceutical company, and the President and Chief Operating Officer of Marion Merrell Dow, Inc., a pharmaceutical company, and a member of its board of directors. From 1973 to 1993, Mr. Markham was associated with Merck & Co., a pharmaceutical company, culminating in his position as President and Chief Operating Officer. Since 2007, Mr. Markham has served as a member of the board of directors of NephroGenex, Inc. and as its board chairman since October 2013. From 2008 until 2016 he also served on the board of directors of CoLuid Pharmaceuticals, Inc. Mr. Markham also served on the board of directors of Acura Pharmaceuticals, Inc. from 2006 to 2013, Anacor Pharmaceuticals, Inc. from 2005 to 2012. Mr. Markham received a B.S. in pharmacy and pharmaceutical sciences from Purdue University.

We believe that Mr. Markham is qualified to serve on the board of directors because of his extensive experience within the life sciences industry, his knowledge of finance and transactions and his historic knowledge of Vaxart's company and its vaccine candidates.

***John P. Richard*** has served as a member of our board of directors since 2013. Mr. Richard is co-founder and Head of Corporate Development for Mereo BioPharma Group plc, a London-based biopharmaceutical company started in 2015. From 2005 until 2015 Mr. Richard was also a partner with Georgia Venture Partners, a seed venture capital firm focused on the biotechnology industry. He currently serves as a non-executive director of Phase4 Partners and serves as a director of Catalyst Biosciences (Nasdaq: CBIO) and QUE Oncology, Inc. Earlier in his career he headed business development for the public companies SEQUUS Pharmaceuticals, VIVUS and Genome Therapeutics, and was co-founder and CEO of Impath. Mr. Richard received his B.S. from Stanford University and an M.B.A. from the Harvard Business School.

We believe Mr. Richard is qualified to serve on the board because of his extensive executive, strategic, financial and business development experience within the biotechnology industry, and having led the business development function at several companies resulting in numerous pharmaceutical alliances.

***Anne M. VanLent*** has served as a member of our board of directors since 2013. Ms. VanLent is President of AMV Advisors, providing corporate strategy and financial consulting services to emerging growth life sciences companies. Ms. VanLent also serves as a director and audit committee chair of Applied Genetics Technologies Corporation (Nasdaq: AGTC) and as a director of Trevi Therapeutics, Inc. Ms. VanLent was the Executive Vice President and Chief Financial Officer of Barrier Therapeutics, Inc., a publicly-traded pharmaceutical company that develops and markets prescription dermatology products, from May 2002 through April 2008. From July 1997 to October 2001, she was the Executive Vice President – Portfolio Management for Sarnoff Corporation, a multidisciplinary research and development firm. From 1985 to 1993, she served as Senior Vice President and Chief Financial Officer of The Liposome Company, Inc., a publicly-traded biopharmaceutical company. During the past five years, Ms. VanLent served as a director, audit committee chair and nominating and governance committee chair of Ocera Pharmaceuticals, Inc. from March 2011 to December 2017, a director of Novelion Pharmaceuticals, Inc. (formerly Aegerion Pharmaceuticals, Inc.) from March 2013 to June 2017, and of Onconova Therapeutics, Inc. from July 2013 to May 2016. Ms. VanLent received a B.A. in Physics from Mount Holyoke College.

We believe Ms. VanLent is qualified to serve on the board of directors because of her extensive leadership and finance experience, and her extensive experience serving as a board member, audit committee member and audit committee chair of numerous public companies in the life sciences industry.

**Family Relationships**

There are no family relationships among the members of the board of directors and executive officers.

**Information Regarding Committees of the Board of Directors**

The board of directors has an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. The board of directors has adopted a written charter for each committee that is available to stockholders on the Investors section of our website at *www.vaxart.com*.

The following table provides membership and meeting information for each of the committees of the Aviragen board of directors from January 1, 2018 to the closing of the Merger on February 13, 2018:

| Name | Audit | Compensation | Nominating and Corporate Governance |
|---|---|---|---|
| Armando Amido[(1)] | | √* | |
| Geoffrey F. Cox, Ph.D | | √ | √* |
| Michael R. Dougherty[(1)] | √ | √ | |
| Michael W. Dunne, M.D.[(1)] | | | √ |
| Joseph M. Patti, M.D.[(1)] | | | |
| Russell H. Plumb[(1)] | | | |
| John P. Richard | √ | | √ |
| Anne M. VanLent | √* | | √ |

* Committee Chairperson

(1) Resigned in February 2018 upon the closing of the Merger.

Upon the closing of the Merger on February 13, 2018, the committees of the board of directors were re-constituted. The following table provides membership for the remainder of 2018 for each of the committees of the board of directors:

| Name | Audit | Compensation | Nominating and Corporate Governance |
|---|---|---|---|
| Wouter W. Latour, M.D. | | | |
| Geoffrey F. Cox, Ph.D.(1) | | | √* |
| Michael J. Finney, Ph.D. | √ | | |
| Jan Leschly(2) | | | √* |
| Richard J. Markham(3) | | √* | √ |
| John P. Richard | √ | √ | |
| Anne M. VanLent | √* | √ | |

* Committee Chairperson

(1) Dr. Cox was appointed chairman of the Nominating and Corporate Governance Committee in December 2018.

(2) Mr. Leschly resigned from the board of directors in November 2018.

(3) Mr. Markham was appointed to the Nominating and Corporate Governance Committee in December 2018.

**Audit Committee**

We have a standing audit committee that is currently composed of three directors (Dr. Finney, Mr. Richard and Ms. VanLent). The board of directors has also determined that Ms. VanLent qualifies as an "audit committee financial expert," as defined in applicable SEC rules. The board of directors made a qualitative assessment of Ms. VanLent's level of knowledge and experience based on a number of factors, including her experience as a chief financial officer for public reporting companies.

**Director Nominations**

No material changes have been made to the procedures by which stockholders may recommend nominees to our board of directors.

**Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than ten percent of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and other equity securities of Vaxart. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations that no other reports were required, during the year ended December 31, 2018, all Section 16(a) filing requirements applicable to our officers, directors and greater than ten percent beneficial owners were complied with, except as follows:

- Two late Form 4's were filed by Dr. Finney covering (i) a pro rata distribution by Life Science Angel Investors II, LLC and LSA Investors Side Fund 2006, LLC of an aggregate of 34,958 shares of our common stock to Dr. Finney in September 2018, and (ii) the purchase of 5,000 shares of our common stock in June 2018. In addition, Dr. Finney filed an amended Form 4 to reflect an additional 1,818 shares of our common stock that were not previously included in his Form 4 filed in connection with the closing of the Merger; and

- A late Form 4 was filed by Mr. Harland covering a pro rata distribution by Life Science Angel Investors II, LLC and LSA Investors Side Fund 2006, LLC of an aggregate of 761 shares of our common stock to Mr. Harland in September 2018.

**Code of Ethics**

We have adopted a Code of Conduct that applies to all officers, directors and employees. The Code of Conduct is available on the Investors section of our website at *www.vaxart.com*. If we make any substantive amendments to the Code of Conduct or grant any waiver from a provision of the Code of Conduct to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website.

**Item 11. Executive Compensation**

The following tables and accompanying narrative disclosure set forth information about the compensation paid or earned by our executive officers during the year ended December 31, 2018. These executive officers were:

- Wouter W. Latour, M.D., our President and Chief Executive Officer;
- Sean N. Tucker, Ph.D., our Chief Scientific Officer;
- John M. Harland, our former Chief Financial Officer;
- Joseph M. Patti, M.S.P.H, Ph.D., former President and Chief Executive Officer of Aviragen; and
- Mark P. Colonnese, former Executive President and Chief Financial Officer of Aviragen.

We refer to these individuals as the "named executive officers."

**Summary Compensation Table**

The following table provides information regarding the total compensation for services rendered in all capacities that was earned by our named executive officers during the year ended December 31, 2018. Upon the closing of the Merger, each of the Aviragen named executive officers resigned.

| Name and Principal Position[1] | Year | Salary | Bonus[2] | Option Awards[3] | All Other Compensation | Total |
|---|---|---|---|---|---|---|
| Wouter W. Latour, M.D.<br>*President and Chief Executive Officer* | 2018 | $ 450,000 | $ — | $ 392,162 | $ 8,250[4] | $ 850,412 |
| Sean N. Tucker, Ph.D.<br>*Chief Scientific Officer* | 2018 | 319,000 | — | 50,398 | 8,610[5] | 378,008 |
| John M. Harland [6]<br>*Former Chief Financial Officer* | 2018 | 310,000 | 35,000 | 64,798 | 8,250[4] | 418,048 |
| Joseph M. Patti, M.S.P.H, Ph.D.<br>*Former President* and *Chief Executive Officer* | 2018<br>2017 | 64,375<br>515,000 | —<br>— | —<br>426,630 | 1,093,873[7]<br>13,973(8) | 1,158,248<br>955,603 |
| Mark P. Colonnese<br>*Former Executive Vice President and Chief Financial Officer* | 2018<br>2017 | 43,725<br>349,800 | —<br>— | —<br>262,541 | 595,656[9]<br>13,656(10) | 639,381<br>625,997 |

(1) Each of Dr. Latour, Dr. Tucker, and Mr. Harland commenced service with Vaxart in February 2018 upon the closing of the Merger. Amounts disclosed for such officers include amounts paid for service with Private Vaxart in 2018.

(2) The Compensation Committee of our Board of Directors did not approve any bonuses for 2018 for our named executive officers except for Mr. Harland, who was awarded a discretionary bonus in June 2018.

( 3 ) Represents the grant date valuation of the awards computed in accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718. See Note 12 to the Consolidated Financial Statements for a discussion of the relevant assumptions used in calculating value pursuant to FASB ASC Topic 718. In addition, please see Note 10 to the Consolidated Financial Statements included in Aviragen's Annual Report on Form 10-K for the fiscal year ended June 30, 2017, filed with the SEC on September 1, 2017, for a discussion of the relevant assumptions used in calculating value pursuant to FASB ASC Topic 718. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Our named executive officers will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options.

(4) Amount shown consists solely of a 401(k) match.

(5) Consists of a 401(k) match of $8,250 and travel reimbursements of $360.

(6) Mr. Harland resigned as our Chief Financial Officer effective December 31, 2018.

(7) Consists of accrued vacation of $5,118, cash severance benefits of $1,086,922, healthcare benefits of $1,375 and supplemental disability payments of $458.

(8) Consists of healthcare benefits of $5,500, supplemental life premiums of $5,724 and supplemental disability payments of$2,749.

(9) Consists of accrued vacation of 28,589, cash severance benefits of $565,116, healthcare benefits of $1,375 and supplemental disability payments of $576.

(10) Consists of healthcare benefits of $5,500, supplemental life premiums of $4,700 and supplemental disability payments of $3,456.

**Employment, Severance and Change in Control Arrangements**

***Vaxart***

*Wouter W. Latour, M.D.*

In May 2011, we extended an offer letter to Wouter W. Latour, M.D., our President and Chief Executive Officer. The offer letter was subsequently amended in October 2011. The offer letter has no specific term and constitutes an at-will employment arrangement. Dr. Latour's current annual base salary is $450,000 and his annual target bonus is 50% of his base salary. The offer letter provided Dr. Latour with a $25,000 signing bonus.

*Sean N. Tucker, Ph.D.*

In May 2006, we extended an offer letter to Sean N. Tucker, Ph.D., our Chief Scientific Officer. The offer letter has no specific term and constitutes an at-will employment arrangement. Dr. Tucker's current annual base salary is $319,000 and his annual target bonus is 30% of his base salary.

*John M. Harland*

In March 2014, we extended an offer letter to John M. Harland, our former Chief Financial Officer. The offer letter has no specific term and constitutes an at-will employment arrangement. In December 2018, Mr. Harland resigned as our Chief Financial Officer effective as of December 31, 2018. Following Mr. Harland's resignation, in January 2019 we extended an offer letter to Mr. Harland and he assumed the position of Vice President, Financial Planning and Administration. Mr. Harland's current annual base salary is $260,000 and his annual target bonus is 30% of his base salary.

*Vaxart Severance Benefit Plan*

In May 2018, we adopted a Severance Benefit Plan pursuant to which selected current and future employees, including the named executive officers, will be eligible for severance benefits under certain circumstances. The Severance Benefit Plan supersedes any acceleration upon change of control benefits that a participant would have been entitled to under any pre-existing agreement between the individual and Vaxart.

The actual amounts that would be paid or distributed to an eligible named executive officer as a result of a termination of employment occurring in the future may be different than those presented below as many factors will affect the amount of any payments and benefits upon a termination of employment. For example, some of the factors that could affect the amounts payable include the named executive officer's base salary and the market price of our common stock. Although we have entered into a participation notice to provide severance payments and benefits in connection with a termination of employment under particular circumstances, Vaxart, or an acquirer, may mutually agree with the named executive officer s to provide payments and benefits on terms that vary from those currently contemplated. In addition to the amounts presented below, each named executive officer would also be able to exercise any previously-vested stock options that he held, in accordance with the terms of those grants and the respective plans pursuant to which they were granted.

To receive any of the severance benefits under these agreements, the named executive officer is required to execute a release of claims against us within 60 days of the qualifying termination and comply with confidentiality provisions.

*Severance Absent a Change in Control*

Under the Severance Plan, a participating individual shall be entitled to receive, in the event of a termination other than in connection with a change in control, (a) cash severance in accordance with our standard payroll practices and subject to standard payroll deductions and withholdings, equal to his annual base salary multiplied by a fraction, the numerator of which is the number of months set forth in his Participation Notice, and the denominator of which is 12, and (b) continuation of his current health insurance coverage, or payment of the premiums for such coverage, for up to the number of months specified in his participation notice. Each named executive officer is eligible to receive the following payments and benefits:

- in the case of Dr. Latour, 100% of annual base salary;
- in the case of Dr. Tucker, 50% of annual base salary;
- in the case of Mr. Harland, 25% of annual base salary; and
- the portion of health insurance premiums paid by Vaxart, prior to the termination, under our group health insurance plans as provided under COBRA, until the earlier of (i) six months (12 months in the case of Dr. Latour, three months in the case of Mr. Harland) after termination, (ii) the expiration of the named executive officer's eligibility for the continuation coverage under COBRA, or (iii) such time as the named executive officer is eligible for health insurance coverage with a subsequent employer.

*Severance in Connection with a Change in Control*

In the case of a termination (following a change in control), if a participating individual is terminated without cause or resigns for good reason (as such terms are defined in the Severance Benefit Plan, either during the three months before or in the 12 months after a change in control, then he will be entitled to receive:

- a lump sum cash severance payment on the first payroll date that occurs more than five (5) days following the effective date of the release signed by the named executive officer, subject to standard payroll deductions and withholdings, equal to a percentage of his annual base salary multiplied by a fraction, the numerator of which is the number of months set forth in his participation notice, and the denominator of which is 12;
- in the case of Dr. Tucker and Mr. Harland, a pro rata amount of their target bonus for the calendar year in which the termination occurs calculated at 100% of target levels as specified in our annual bonus plan or program in effect immediately prior to the effective date of the change in control and a fraction, the numerator of which is the number of months of the participant's employment during the calendar year in which the change of control occurs, and the denominator of which is 12;
- continuation of his current health insurance coverage, or payment of the premiums for such coverage, for up to the number of months specified in his participation notice under the Severance Benefit Plan; and
- accelerated vesting of then outstanding compensatory equity awards as to all unvested shares.

Each named executive officer is eligible to receive the following payments and benefits:

- in the case of Dr. Latour, 150% of annual base salary;
- in the case of Dr. Tucker, 100% of annual base salary;
- in the case of Mr. Harland, 50% of annual base salary;
- in the case of Dr. Tucker and Mr. Harland, prorated target bonus for the calendar year in which the termination occurs;
- full acceleration of vesting of any stock options to purchase common stock granted to the named executive officer; and
- health insurance premiums under our group health insurance plans as provided under COBRA, to the extent such COBRA premiums exceed the costs previously paid by the named executive officer for group health insurance coverage while employed by us, until the earlier of (i) 12 months (18 months in the case of Dr. Latour, six months in the case of Mr. Harland) after a change in control, (ii) the expiration of the named executive officer's eligibility for the continuation coverage under COBRA, or (iii) such time as the named executive officer is eligible for health insurance coverage with a subsequent employer.

***Aviragen***

*Joseph M. Patti, Ph.D.*

Joseph M. Patti, Ph.D., ceased to be President and Chief Executive Officer of Aviragen and an employee of Aviragen upon the closing of the Merger. Under the terms of Dr. Patti's employment agreement, in the event Dr. Patti's employment was terminated by Dr. Patti for good reason (as defined in Dr. Patti's employment agreement) or by Aviragen for any reason other than cause, death or disability, in either case, within three months prior to or one year after the consummation of a change in control, Aviragen would pay Dr. Patti, subject to Dr. Patti's execution, delivery and non-revocation of a release, a lump sum equal to the sum of (i) any cash incentive compensation earned and unpaid through such termination; plus (ii) Dr. Patti's salary for 24 months; plus (iii) the product of two times (2x) the cash incentive compensation paid to Dr. Patti in respect of the most recent fiscal year prior to the year in which such termination occurs; plus (iv) an amount equal to the present value of the premium payments that would be made by Aviragen if Dr. Patti were to continue to be covered under Aviragen's group health, life and disability insurance for 24 months, which amount will be determined by Aviragen in its sole discretion. Dr. Patti resigned with good cause upon the closing of the Merger and received an aggregate of $1,086,922 in cash severance benefits.

*Mark P. Colonnese*

Mark P. Colonnese ceased to be Executive Vice President and Chief Financial Officer and an employee of Aviragen upon the closing of the Merger. Under the terms of Mr. Colonnese's employment agreement, in the event Mr. Colonnese's employment was terminated by Mr. Colonnese for good reason (as defined in Mr. Colonnese's employment agreement) or by Aviragen for any reason other than cause, death or disability, in either case, within 60 days prior to or one year after the consummation of a change in control, Aviragen would pay Mr. Colonnese, subject to Mr. Colonnese's execution, delivery and nonrevocation of a release, a lump sum equal to the sum of (i) any earned but unpaid cash incentive compensation for the fiscal year immediately preceding the fiscal year in which such termination occurs; plus (ii) Mr. Colonnese's base salary for 18 months; plus (iii) the product of one and a half times (1.5x) the cash incentive compensation paid to Mr. Colonnese in respect of the most recent fiscal year prior to the year in which such termination occurs, plus (iv) an amount equal to the present value of the premium payments that would be made by Aviragen if Mr. Colonnese were to continue to be covered under Aviragen's group health, life and disability insurance for 18 months, which amount will be determined by Aviragen in its sole discretion. Mr. Colonnese resigned with good cause upon the closing of the Merger and received an aggregate of $565,116 in cash severance benefits.

*Acceleration of Unvested Aviragen Equity Awards*

All outstanding stock options held by Aviragen's executive officers and directors were accelerated and fully vested in accordance with their terms upon the closing of the Merger and/or the termination of optionees' employment in connection therewith. Please see the section above titled "*Outstanding Equity Awards at December 31, 2018"* for information regarding stock options held by Dr. Patti and Mr. Colonnese.

**401(k) Plan**

Aviragen did not provide pension arrangements or post-retirement health coverage for its executive officers or employees. Aviragen's executive officers and other eligible employees were eligible to participate in its 401(k) defined contribution plan. Aviragen made matching contributions to participants in the 401(k) plan in an amount equal to 25% of the employee's deferral up to a maximum of 4% of an employee's salary, subject to statutory limits.

We maintain a tax-qualified retirement plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees are able to defer eligible compensation up to certain Code limits, which are updated annually. We have the ability to make matching and discretionary contributions to the 401(k) plan, but have not done so to date. Employee contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participant's directions. Employees are immediately and fully vested in their own contributions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code, with the related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan are deductible by us when made, and contributions and earnings on those amounts are not taxable to the employees until withdrawn or distributed from the 401(k) plan. Vaxart makes matching contributions to participants in the 401(k) plan in an amount equal to the employee's deferral up to a maximum of 3% of the employee's annual eligible earnings.

**Pension Benefits**

The named executive officers did not participate in, or otherwise receive any benefits under any pension or retirement plan Vaxart or Aviragen sponsored during 2018.

**Nonqualified Deferred Compensation**

The named executive officers did not participate in, or earn any benefits under, a nonqualified deferred compensation plan Vaxart or Aviragen sponsored during 2018.

**Outstanding Equity Awards at December 31, 2018**

The following table presents, for each of our named executive officers, information regarding outstanding stock options held as of December 31, 2018.

| | Option Awards | | | | |
|---|---|---|---|---|---|
| Name | Grant Date of Option Award | Number of Securities Underlying Unexercised Options (#) Exercisable | Number of Securities Underlying Unexercised Options (#) Unexercisable | Options Exercise Price ($) | Option Expiration Date |
| Wouter W. Latour, M.D. | 6/29/2011 (1) | 6,535 | — | $ 8.03 | 6/28/2021 |
| | 11/3/2011 (1) | 9,441 | — | 8.03 | 11/2/2021 |
| | 8/8/2013 (1) | 13,255 | — | 6.49 | 8/7/2023 |
| | 5/8/2014 (1) | 14,908 | — | 8.03 | 5/7/2024 |
| | 7/23/2015 (2) | 10,576 | 2,265 | 17.49 | 7/22/2025 |
| | 7/23/2015 (2) | 5,279 | — | 17.49 | 7/22/2025 |
| | 3/25/2016 (3) | 717 | 3,354 | 12.98 | 3/24/2026 |
| | 3/25/2016 (3) | 6,660 | — | 12.98 | 3/24/2026 |
| | 6/24/2017 (4) | — | 14,782 | 4.07 | 6/23/2027 |
| | 6/24/2017 (4) | 8,869 | — | 4.07 | 6/23/2027 |
| | 5/25/2018 (5) | — | 35,284 | 5.17 | 5/24/2028 |
| | 5/25/2018 (5) | — | 75,416 | 5.17 | 5/24/2028 |
| John M. Harland | 5/8/2014 (1) | 9,563 | — | 8.03 | 5/7/2024 |
| | 7/23/2015 (2) | 7,223 | 1,032 | 17.49 | 7/22/2025 |
| | 3/25/2016 (3) | 2,810 | 1,277 | 12.98 | 3/24/2026 |
| | 6/24/2017 (4) | 2,642 | 4,405 | 4.07 | 6/23/2027 |
| | 5/25/2018 (5) | — | 18,000 | 5.17 | 5/24/2028 |
| Sean N. Tucker, Ph.D. | 8/27/2010 (1) | 4,026 | — | 6.49 | 8/26/2020 |
| | 3/30/2011 (1) | 1,006 | — | 6.49 | 3/29/2021 |
| | 4/13/2012 (1) | 3,020 | — | 8.03 | 4/12/2022 |
| | 8/8/2013 (1) | 10,523 | — | 6.49 | 8/7/2023 |
| | 5/8/2014 (1) | 11,604 | — | 8.03 | 5/7/2024 |
| | 7/23/2015 (2) | 8,396 | 1,259 | 17.49 | 7/22/2025 |
| | 7/23/2015 (2) | 412 | — | 17.49 | 7/22/2025 |
| | 3/25/2016 (3) | 3,694 | 2,416 | 12.98 | 3/24/2026 |
| | 3/25/2016 (3) | 1,621 | — | 12.98 | 3/24/2026 |
| | 6/24/2017 (4) | 3,397 | 5,663 | 4.07 | 6/23/2027 |
| | 5/25/2018 (5) | — | 14,000 | 5.17 | 5/24/2028 |
| Joseph M. Patti, M.S.P.H., Ph.D. | 4/3/2017 (6) | 59,090 | — | 7.22 | 8/13/2019 |
| Mark P. Colonnese | 4/3/2017 (7) | 36,363 | — | 7.22 | 8/13/2019 |

(1) The shares subject to this option are fully vested.

(2) The unvested shares vest in equal monthly installments through July 23, 2019, subject to the executive officer's continued service with us through each relevant vesting date.

(3) The unvested shares vest in equal monthly installments through March 25, 2020, subject to the executive officer's continued service with us through each relevant vesting date.

(4) The unvested shares vest in equal monthly installments through June 24, 2021, subject to the executive officer's continued service with us through each relevant vesting date.

(5) The unvested shares vest in equal monthly installments through May 25, 2022, subject to the executive officer's continued service with us through each relevant vesting date.

(6) The vesting of all shares under this stock option was accelerated in full upon Dr. Patti's resignation following the Merger.

(7) The vesting of all shares under this stock option was accelerated in full upon Mr. Colonnese's resignation following the Merger.

**Director Compensation**

During 2018, our non-employee directors were compensated in the following manner under our director compensation program.

*Annual and Meeting Fees.*During 2018, our non-employee directors received the following cash compensation for their service on the board of directors and its committees:

- $37,000 annual cash retainer;
- $20,000 for the non-executive chairman of the board and $15,000 for lead director (if applicable);
- $17,500 for the chair of the Audit Committee and $8,750 for each of its other members;
- $12,500 for the chair of the Compensation Committee and $6,250 for each of its other members; and
- $9,000 for the chair of the Nominating and Corporate Governance Committee and $4,500 for each of its other members.
- $13,000 for the chair of the Aviragen Transactions Committee and $10,000 for each of its other members was paid in connection with and at the conclusion of the Merger.

*Equity Awards*. The Aviragen non-employee director equity compensation policy provided that each non-employee director would receive, upon the initial effective date of such director's appointment, a stock option award to purchase 3,182 shares of Aviragen's common stock under its 2016 Equity Incentive Plan, 33% of which would vest on the first, second and third anniversary of the grant date. In addition, each non-employee director would receive an annual award of options to purchase 1,818 shares of the Aviragen's common stock under its 2016 Equity Incentive Plan that will vest on the one year anniversary of the grant date.

The exercise price of all stock options granted to the Aviragen directors was equal to the fair market value of Aviragen's common stock on the date of the grant. As of the closing of the Merger, Aviragen's non-employee directors held 14,888 unvested stock options and 92,745 vested stock options in the aggregate, with a weighted average exercise price of $34.93.

Since the closing of the Merger in February 2018, we have not granted any stock options to our directors.

Non-employee directors receive no other form of remuneration, perquisites or benefits, but are reimbursed for their expenses in attending meetings, including travel, meal and other expenses incurred to attend meetings solely among the non-employee directors.

**Director Compensation — 2018**

The following table provides director compensation information for each of the non-employee directors of the Aviragen board of directors serving from January 1, 2018 until their resignation in connection with the closing of the Merger in February 2018:

| Name | Fees Earned or Paid in Cash | Total |
|---|---|---|
| Michael Dougherty | $ 6,345 | $ 6,345 |
| Russell Plumb | 6,955 | 6,955 |
| Armando Anido | 6,040 | 6,040 |
| Michael W. Dunne, M.D. | 5,064 | 5,064 |

The following table provides director compensation information for each of our non-employee directors, including the non-employee directors of Aviragen who continued to serve on the board of directors following the closing of the Merger:

| Name | Fees Earned or Paid in Cash | Total |
|---|---|---|
| Geoffrey F. Cox, Ph.D. | $ 42,804 | $ 42,804 |
| Michael J. Finney, Ph.D. | 40,158 | 40,158 |
| Jan Leschly(1) | 34,878 | 34,878 |
| Richard J. Markham | 61,006 | 61,006 |
| John P. Richard | 51,776 | 51,776 |
| Anne M. VanLent | 62,355 | 62,355 |

(1) Resigned as a member of the board of directors in November 2018.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

**Equity Compensation Plans at December 31, 2018**

The following table provides certain information with respect to all equity compensation plans in effect as of December 31, 2018.

| Plan Category | Number of Securities to Be Issued Upon Exercise of Outstanding Options (a) | Weighted-Average Exercise Price of Outstanding Options (b) | Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c) |
|---|---|---|---|
| Equity compensation plans approved by security holders | 615,961(1) | $ 7.57 | 223,377(2) |
| Equity compensation plans not approved by security holders | 249,202(3) | $ 9.50 | — |
| Total | 865,163 | $ 8.13 | 223,377 |

(1) Reflects shares of common stock issuable upon the exercise of outstanding stock options granted under various plans that were formerly approved by Aviragen's stockholders.

(2) Reflects shares of common stock that are available for future issuance under the 2016 Equity Incentive Plan.

(3) Reflects shares of common stock issuable upon the exercise of outstanding stock options granted under the Vaxart, Inc. Amended and Restated 2007 Equity Incentive Plan, which we assumed upon the closing of the Merger in February 2018. This plan expired in July 2017 and no further awards may be made under this plan.

**Principal Stockholders**

The following table sets forth certain information regarding the ownership of our common stock as of December 31, 2018 by:

- each director;
- each current executive officer
- all of our executive officers and directors as a group; and
- all those known by us to be beneficial owners of more than five percent of our outstanding common stock.

This table is based upon information supplied by officers, directors and principal stockholders and Schedules 13G filed with the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, the Company we believe that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 7,141,189 shares outstanding on December 31, 2018, adjusted as required by rules promulgated by the SEC.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Vaxart, Inc., 290 Utah Ave., Suite 200 , South San Francisco, California 94080.

| Name of Beneficial Owner | Beneficial Ownership | |
|---|---|---|
| | Shares | % |
| *Greater than 5% Stockholders:* | | |
| Entities affiliated with Care Capital [1] | 2,799,424 | 39.2% |
| *Executive Officers and Directors:* | | |
| Geoffrey F. Cox, Ph.D. [2] | 8,567 | * |
| Michael J. Finney, Ph.D. | 270,754 | 3.8 |
| John M. Harland [3] | 23,636 | * |
| Wouter W. Latour, M.D. [4] | 78,051 | 1.1 |
| Richard J. Markham [5] | — | * |
| John P. Richard [6] | 9,543 | * |
| Sean N. Tucker, Ph.D. [7] | 130,710 | 1.8 |
| Anne M. VanLent [8] | 12,724 | * |
| All executive officers and directors as a group (8 persons) | 533,985 | 7.3 |

* Represents beneficial ownership of less than one percent.

(1) Includes (a) 2,753,441 shares held by Care Capital Investments III, LP ("Investments III") and (b) 45,983 shares held by Care Capital Offshore Investments III, LP ("Offshore III"). Care Capital III LLC is the general partner of Investments III LP and Offshore III (collectively, "Care Capital") and as a result, Care Capital III LLC has the ultimate power to vote or direct the vote and to dispose or direct the disposition of such shares. The address for each of these entities is P.O. Box 276, Avon by the Sea, New Jersey 07717.

(2) Includes (a) 388 shares held by Dr. Cox's spouse, and (b) 8,179 shares issuable pursuant to stock options exercisable within 60 days of December 31, 2018.

(3) Includes (a) 761 shares held directly by Mr. Harland, and (b) 22,875 shares issuable pursuant to stock options exercisable within 60 days of December 31, 2018.

(4) Consists of 78,051 shares issuable pursuant to stock options exercisable within 60 days of December 31, 2018.

(5) Mr. Markham ceased to serve as a managing member of Care Capital effective December 31, 2018, and does not beneficially own any shares.

(6) Consists of 9,543 shares issuable pursuant to stock options exercisable within 60 days of December 31, 2018.

(7) Includes (a) 47,653 shares held directly by Dr. Tucker, (b) 25,388 shares held by Frances Chang and Sean Tucker, (c) 9,060 shares held by Dr. Tucker's spouse, and (d) 48,609 shares issuable pursuant to stock options exercisable within 60 days of December 31, 2018.

(8) Includes (a) 3,181 shares held directly by Ms. VanLent, and (b) 9,543 shares issuable pursuant to stock options exercisable within 60 days of December 31, 2018.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

**Related-Party Transaction Policy and Procedures**

We have adopted a written Related Party Transaction Policy that sets forth our policies and procedures regarding the identification, review, consideration and approval or ratification of "related party transactions." For purposes of our policy only, a "related party transaction" is a transaction, arrangement or relationship (including indebtedness or a guarantee of indebtedness) or any series of similar transactions, arrangements or relationships in which we and any "related party" are, were or will be participants involving an amount that exceeds $120,000 and in which any "related party" has a direct or indirect material interest. Transactions involving compensation for services provided to us as an employee, director, consultant or similar capacity by a related party are not covered by this policy. A related party is any executive officer, director, nominee to become a director or more than 5% stockholder of us, including any of their immediate family members, and any entity owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related party transaction, management must present information regarding the proposed related party transaction to the Audit Committee (or, where Audit Committee approval would be inappropriate, to another independent body of the Board) for consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related parties, the benefits to us of the transaction and whether any alternative transactions were available. To identify related party transactions in advance, we rely on information supplied by its executive officers, directors and certain significant stockholders. In considering related party transactions, the Audit Committee takes into account the relevant available facts and circumstances including, but not limited to (a) the risks, costs and benefits to us, (b) the impact on a director's independence in the event the related party is a director, immediate family member of a director or an entity with which a director is affiliated, (c) the terms of the transaction, (d) the availability of other sources for comparable services or products and (e) the terms available to or from, as the case may be, unrelated third parties or to or from employees generally. In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval. The policy requires that, in determining whether to approve, ratify or reject a related party transaction, the Audit Committee consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, the best interests of us and our stockholders, as the Audit Committee determines in the good faith exercise of its discretion.

**Certain Related-Person Transactions**

***Indemnity Agreements***

We have entered into indemnity agreements with our executive officers and directors which provide, among other things, that we will indemnify such officer or director, under the circumstances and to the extent provided for therein, for expenses, damages, judgments, fines and settlements he or she may be required to pay in actions or proceedings which he or she is or may be made a party by reason of his or her position as a director, officer or other agent of ours, and otherwise to the fullest extent permitted under Delaware law and our Bylaws.

***Offer Letters***

We have entered into offer letters, employment agreements and change in control arrangements with our executive officers. For more information regarding these agreements, see "Item 11. Executive Compensation—Employment, Severance and Change in Control Agreements."

***Equity Grants***

We have granted stock options to our executive officers and certain members of our board of directors. For a description of our executive officers' options, see "Item 11. Executive Compensation—Outstanding Equity Awards at December 31, 2018." There were no awards to non-employee directors in 2018.

**Independence of The Board of Directors**

As required under the Nasdaq Stock Market, or Nasdaq, listing standards, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by the board of directors. The board of directors consults with our counsel to ensure that its determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and Vaxart, our senior management and our independent auditors, the board of directors has affirmatively determined that all of our directors, other than Dr. Latour due to his position as our President and Chief Executive Officer, are independent within the meaning of the applicable Nasdaq listing standards.

## Item 14. Principal Accounting Fees and Services

**Current Principal Accountant Fees and Services**

**KPMG LLP**

In February 2018, upon the closing of the Merger, the combined company dismissed Ernst & Young LLP as our independent registered accounting firm and appointed KPMG LLP as our new independent registered accounting firm. KPMG LLP has audited the financial statements of Private Vaxart since February 2014. Private Vaxart was determined to be the accounting acquirer based upon the terms of the merger agreement resulting in a change to the combined company's fiscal year to December 31, effective as of the closing of the Merger.

The following table represents aggregate fees billed to Private Vaxart for the year ended December 31, 2017, and to the combined company for the year ended December 31, 2018, by KPMG LLP.

| | Year Ended December 31, | |
|---|---|---|
| | 2017 | 2018 |
| Audit Fees[1] | $ 290,760 | $ 559,000 |
| Audit-Related Fees | — | — |
| Tax Fees | — | — |
| All Other Fees[2] | — | 1,780 |
| Total Fees | $ 290,760 | $ 560,780 |

(1) Audit Fees consisted of fees for professional services rendered for the audits of our financial statements which were billed during the respective year, including the audits of our annual financial statements and reviews of our interim quarterly reports, and services provided in connection with SEC filings, including consents and comfort letters.

(2) All Other Fees consisted of access to KPMG's Accounting Research Online website.

As Vaxart was private during 2017, none of the KPMG LLP fees were pre-approved. Following the Merger, all the KPMG LLP fees incurred were pre-approved by our Audit Committee.

During the years ended December 31, 2017 and 2018, and the subsequent interim period through February 13, 2018, neither Vaxart, Aviragen, nor anyone on their behalf consulted with KPMG LLP, regarding either (i) the application of accounting principles to a specific transaction, completed or proposed, or the type of audit opinion that might be rendered on Vaxart's financial statements, and neither a written report nor oral advice was provided to Vaxart that KPMG LLP concluded was an important factor considered by Vaxart in reaching a decision as to any accounting, auditing or financial reporting issue or (ii) any matter that was either the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) or a reportable event (as described in Item 304(a)(1)(v) of Regulation S-K).

**Former Principal Accountant Fees and Services**

PricewaterhouseCoopers LLP, an independent registered public accounting firm, audited Aviragen Therapeutics, Inc.'s financial statements for the fiscal years ended June 30, 2014 and 2015. PricewaterhouseCoopers LLP was dismissed and Ernst & Young LLP was engaged by Aviragen in March 2016. In February 2018, upon the closing of the Merger, the combined company dismissed Ernst & Young LLP as its independent registered public accounting firm and appointed KPMG LLP as the new independent registered public accounting firm.

**Ernst & Young LLP**

The following table represents aggregate fees billed to Aviragen for the fiscal year ended June 30, 2017 and for the period July 1, 2017 to the closing of the Merger on February 13, 2018 by Ernst & Young LLP.

| | Fiscal Year Ended June 30 2017 | For the Period July 1, 2017 to February 13, 2018 |
|---|---|---|
| Audit Fees[1] | $ 411,351 | $ 134,046 |
| Audit-Related Fees | — | — |
| Tax Fees | — | — |
| All Other Fees | — | — |
| Total Fees | $ 411,351 | $ 134,046 |

(1) Audit Fees consisted of fees for professional services rendered for the audits of Aviragen financial statements which were billed during the respective fiscal year, including the audits of Aviragen's annual financial statements and reviews of Aviragen's interim quarterly reports, and services provided in connection with SEC filings, including consents and comfort letters

All the fees incurred were pre-approved by the Aviragen Audit Committee.

The reports of Ernst & Young LLP on Aviragen's consolidated financial statements for the fiscal years ended June 30, 2017 and 2016 did not contain an adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope, or accounting principles. During the fiscal years ended June 30, 2017 and 2016, and the subsequent interim period through February 13, 2018 there were no: (1) disagreements (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) with Ernst & Young LLP on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreement if not resolved to the satisfaction of Ernst & Young LLP would have caused Ernst & Young LLP to make reference thereto in its reports on the consolidated financial statements for such years, or (2) reportable events (as described in Item 304(a)(1)(v) of Regulation S-K).

During the two most recent fiscal years and through March 23, 2016, the date of the engagement of Ernst & Young LLP, neither Aviragen nor any person on its behalf consulted with Ernst & Young LLP with respect to either (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on Aviragen's consolidated financial statements or (ii) any matter that was either the subject of a "disagreement" or a "reportable event" as such terms are described in Items 304(a)(1)(iv) or 304(a)(1)(v), respectively, of Regulation S-K promulgated under the Exchange Act.

**PricewaterhouseCoopers LLP**

The following table represents aggregate fees billed to Aviragen for the fiscal year ended June 30, 2017 by PricewaterhouseCoopers LLP. No fees were billed to Aviragen for the period of July 1, 2017 to February 13, 2018.

| | Fiscal Year Ended June 30, 2017 |
|---|---|
| Audit Fees | $ — |
| Audit-Related Fees[1] | 19,000 |
| Tax Fees | — |
| All Other Fees | — |
| Total Fees | $ 19,000 |

(1) Audit-Related Fees consisted of fees for professional services which were billed during the year, including services provided in connection with SEC filings, including consents.

All the fees incurred were pre-approved by the Aviragen Audit Committee and no fees were incurred subsequent to June 30, 2017.

The reports of PricewaterhouseCoopers LLP on Aviragen Therapeutics, Inc.'s consolidated financial statements as of and for the fiscal years ended June 30, 2014 and 2015 did not contain an adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principle.

During Aviragen Therapeutics, Inc.'s fiscal years ended June 30, 2014 and 2015 and in the subsequent interim period through March 23, 2016, there were no disagreements with PricewaterhouseCoopers LLP on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements if not resolved to the satisfaction of PricewaterhouseCoopers LLP would have caused them to make reference to the subject matter of the disagreements in connection with their audit reports on the consolidated financial statements for such years, nor were there any "reportable events" as such term is defined in Item 304(a)(1)(v) of Regulation S-K promulgated under the Exchange Act.

**Pre-Approval Policies and Procedures**

The Audit Committee has adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by our independent registered public accounting firm, KPMG LLP. The policy generally pre-approves specified services in the defined categories of audit services, audit-related services and tax services up to specified amounts. Pre-approval may also be given as part of the Audit Committee's approval of the scope of the engagement of the independent auditor or on an individual, explicit, case-by-case basis before the independent auditor is engaged to provide each service. The pre-approval of services may be delegated to one or more of the Audit Committee's members, but the decision must be reported to the full Audit Committee at its next scheduled meeting.

The Audit Committee has determined that the rendering of services other than audit services by KPMG LLP is compatible with maintaining the principal accountant's independence.

# PART IV

**Item 15. Exhibits and Financial Statement Schedules**

**Financial Statement Schedules**

All financial statement schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

**Exhibits**

The following documents are being filed with this Annual Report on Form 10-K.

(1) Financial Statements (see "Financial Statements and Supplementary Data" at Item 8 and incorporated herein by reference).

(2) Financial Statement Schedules (Schedules to the Financial Statements have been omitted because the information required to be set forth therein is not applicable or is shown in the accompanying Financial Statements or notes thereto).

(3) Exhibits.

## EXHIBIT INDEX

| Exhibit Number | Description of Document | Incorporated by Reference | | | |
|---|---|---|---|---|---|
| | | Schedule/Form | File Number | Exhibit | Filing Date |
| 2.1 | Agreement and Plan of Merger and Reorganization dated October 27, 2017, by and among Aviragen Therapeutics, Inc., Vaxart, Inc. and Agora Merger Sub, Inc. | 8-K | 001-35285 | 2.1 | October 30, 2017 |
| 2.2 | Amendment No. 1, dated as of February 7, 2018, to the Agreement and Plan of Merger and Reorganization dated October 27, 2017, by and among Aviragen Therapeutics, Inc., Vaxart, Inc. and Agora Merger Sub, Inc. | 8-K | 001-35285 | 2.1 | February 7, 2018 |
| 3.1 | Restated Certificate of Incorporation of Aviragen Therapeutics, Inc. | 10-K | 001-35285 | 3.1 | September 13, 2016 |
| 3.2 | Certificate of Amendment to Restated Certificate of Incorporation of AviragenTherapeutics, Inc. | 8-K | 001-35285 | 3.1 | February 20, 2018 |
| 3.3 | Certificate of Amendment to Restated Certificate of Incorporation of Vaxart, Inc. | 8-K | 001-35285 | 3.2 | February 20, 2018 |
| 3.4 | Restated By-laws of Aviragen Therapeutics,Inc. | 10-K | 001-35285 | 3.2 | September 13, 2016 |
| 4.1 | Reference is made to Exhibits 3.1 to 3.3 | | | | |
| 4.2 | Specimen Common Stock Certificate | S-3 | 333-228910 | 4.2 | December 20, 2018 |
| 10.1+ | Collaboration and License Agreement dated September 29, 2003, between Biota Holdings Limited and Sankyo Co., Ltd. | 10-Q | 001-35285 | 10.5 | May 10, 2013 |
| 10.2+ | Amendment #1 to Collaboration and License Agreement dated June 30, 2005, between Biota Holdings Limited, Biota Scientific Management Pty. Ltd. and Sankyo Company, Ltd. | 10-Q | 001-35285 | 10.6 | May 10, 2013 |
| 10.3 | Amendment #2 to Collaboration and License Agreement, dated March 27, 2009, between Biota Holdings Limited, Biota Scientific Management Pty. Ltd. and Daiichi Sankyo Company, Limited | 10-Q | 001-35285 | 10.7 | May 10, 2013 |
| 10.4+ | Commercialization Agreement dated March 27, 2009, between Biota Holdings Limited, Biota Scientific Management Pty. Ltd and Daiichi Sankyo Company, Ltd. | 10-Q | 001-35285 | 10.8 | May 10, 2013 |
| 10.5+ | Contract dated March 31, 2011, between Biota Scientific Management Pty. Ltd. and Office of Biomedical Advanced Research and Development Authority within the Office of the Assistant Secretary for preparedness and Response at the U.S. Department of Health and Human Services | 10-Q | 001-35285 | 10.9 | May 10, 2013 |
| 10.6+ | Research and License Agreement dated February 21, 1990, by and among Biota Scientific Management Pty. Ltd., Biota Holdings Limited, Glaxo Australia Pty. Ltd. and Glaxo Group Limited | 10-K | 001-35285 | 10.6 | September 27, 2013 |
| 10.7# | 2007 Omnibus Equity and Incentive Plan (included as Appendix A to the proxy statement) | DEF 14A | 000-04829 | - | April 12, 2007 |
| 10.8# | Form of Employee Stock Option Agreement under the 2007 Omnibus Equity and Incentive Plan | 8-K | 001-35285 | 10.1 | December 10, 2013 |

| Exhibit Number | Description of Document | Incorporated by Reference | | | |
|---|---|---|---|---|---|
| | | Schedule/Form | File Number | Exhibit | Filing Date |
| 10.9+ | Royalty Interest Acquisition Agreement by and between Aviragen Therapeutics, Inc., Biota Holdings Pty Ltd, Biota Scientific Management Pty. Ltd. and HealthCare Royalty Partners III, L.P. dated April 22, 2016 | 8-K | 001-35285 | 10.1 | April 26, 2016 |
| 10.10 | Protective Rights Agreement between Aviragen Therapeutics, Inc. and HealthCare Royalty Partners III, L.P. dated April 22, 2016 | 8-K | 001-35285 | 10.2 | April 26, 2016 |
| 10.11# | Form of Employee Stock Option Agreement under the 2016 Equity Incentive Plan | 10-Q | 001-35285 | 10.1 | May 8, 2017 |
| 10.12# | 2016 Equity Incentive Plan (included as Appendix A to the proxy statement) | DEF 14A | 001-35285 | - | September 27, 2016 |
| 10.13# | Director Stock Option Agreement | S-4 | 333-222009 | 10.22 | December 12, 2017 |
| 10.14 | Form of Indemnification Agreement by and between Vaxart, Inc. and its Directors and Executive Officers | 8-K | 001-35285 | 10.3 | February 20, 2018 |
| 10.15# | Vaxart, Inc. Amended and Restated 2007 Equity Incentive Plan, Stock Option Agreement, form of Notice of Stock Option Grant, form of Additional Terms and Conditions to Option and Stock Option Exercise Agreement | S-4/A | 333-222009 | 10.24 | December 29, 2017 |
| 10.16# | Offer Letter, dated May 25, 2011, and Amendment to Offer Letter and Option Grant Agreement, dated October 1, 2011, by and between Vaxart, Inc. and Wouter W. Latour, M.D. | S-4/A | 333-222009 | 10.25 | December 29, 2017 |
| 10.17 | Industrial Lease dated October 28, 2013, by and between Vaxart, Inc. and Oyster Point LLC | S-4/A | 333-222009 | 10.26 | December 29, 2017 |
| 10.18 | Lease Agreement dated April 17, 2015, by and between Vaxart, Inc. and CRP Edgewater, LLC | S-4/A | 333-222009 | 10.27 | December 29, 2017 |
| 10.19 | Loan and Security Agreement dated December 22, 2016, by and between Vaxart, Inc. and Oxford Finance LLC | S-4/A | 333-222009 | 10.28 | December 29, 2017 |
| 10.20 | Second Amendment to the Loan Agreement, dated February 13, 2018, between Vaxart, Inc. and Oxford Finance LLC. | 8-K | 001-35285 | 10.1 | February 20, 2018 |
| 10.21# | Severance Benefit Plan and Form of Severance Benefit Plan Participation Notice. | 8-K | 001-35285 | 10.1 | June 6, 2018 |
| 10.22 | Settlement Agreement by and among Vaxart, Inc., Digirad Corporation, East Hill Management Company, LLC, and Aviragen Therapeutics, Inc. | 8-K | 001-35285 | 10.1 | February 9, 2018 |
| 10.23 | Form of Sales Agreement dated December 19, 2018 by and between Vaxart, Inc. and B. Riley FBR, Inc. | S-3 | 333-228910 | 1.2 | December 02, 2018 |
| 10.24 | Amended and Restated Warrant issued to Oxford Finance LLC, dated February 13, 2018 | 8-K | 001-35285 | 10.2 | February 20, 2018 |
| 21.1* | Subsidiaries of the Registrant | | | | |
| 23.1* | Consent of Independent Registered Public Accounting Firm | | | | |
| 24.1* | Power of Attorney. Reference is made to the signature page hereto | | | | |
| 31.1* | Certifications of Principal Executive and Financial Officer pursuant to Exchange Act Rule, 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | |

| Exhibit Number | Description of Document | Incorporated by Reference | | | |
|---|---|---|---|---|---|
| | | Schedule/Form | File Number | Exhibit | Filing Date |
| 32.1*§ | Certification of Principal Executive and Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | |
| 101 * | The following financial information from the Company's Annual Report on Form 10-K for the year ended December 31, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets as of December 31, 2018 and 2017, (ii) the Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2018 and 2017, (iii) the Consolidated Statements of Stockholders' Equity (Deficit) for the two years ended December 31, 2018, (iv) the Consolidated Statements of Cash Flows for the years ended December 31, 2018 and 2017, and (v) Notes to the Consolidated Financial Statements | | | | |

_____

* Filed herewith

\# Management contract or compensation plan or arrangement

\+ Confidential portions of this exhibit have been omitted and filed separately with the Commission pursuant to confidential treatment granted under Rule 24b-2 promulgated under the Exchange Act

§ In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certification furnished in Exhibit 32.1 hereto is deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Exchange Act. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference

**Item 16. Form 10-K Summary**

None.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

VAXART, INC.

Date: February 6, 2019

By: /s/ WOUTER W. LATOUR, M.D.
Wouter W. Latour, M.D.
*President and Chief Executive Officer*

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Wouter W. Latour, M.D. and Margaret A. Echerd, and each of them, as his or her attorneys-in-fact, with the power of substitution, for him or her in any and all capacities, to sign any amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorneys-in-fact, and each of them, or his or her substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| SIGNATURE | TITLE | DATE |
|---|---|---|
| /s/ WOUTER W. LATOUR, M.D.<br>Wouter W. Latour, M.D. | President, Chief Executive Officer and Director<br>*(Principal Executive Officer and Principal Financial Officer)* | February 6, 2019 |
| /s/ MARGARET A. ECHERD<br>Margaret A. Echerd | Vice President, Corporate Controller<br>*(Principal Accounting Officer)* | February 6, 2019 |
| /s/ RICHARD J. MARKHAM<br>Richard J. Markham | Chairman of the Board | February 6, 2019 |
| /s/ GEOFFREY F. COX<br>Geoffrey F. Cox, Ph.D. | Director | February 6, 2019 |
| /s/ MICHAEL J. FINNEY<br>Michael J. Finney, Ph.D. | Director | February 6, 2019 |
| /s/ JOHN P. RICHARD<br>John P. Richard | Director | February 6, 2019 |
| /s/ ANNE M. VANLENT<br>Anne M. VanLent | Director | February 6, 2019 |

**Exhibit 21.1**

**SUBSIDIARIES OF THE REGISTRANT**

| Name | Jurisdiction |
|---|---|
| Vaxart Biosciences, Inc. | Delaware |
| Biota Holdings Pty, Ltd. | Australia |
| Biota Scientific Management Pty, Ltd. | Australia |
| Biota Europe Limited | United Kingdom |
| Anaconda Pharma, S.A.S. | France |

**Exhibit 23.1**

**Consent of Independent Registered Public Accounting Firm**

The Board of Directors
Vaxart, Inc.:

We consent to the incorporation by reference in the registration statements (No. 333-228910) on Form S-3 and (No. 333-225475, 333-215141, 333-143238) on Form S-8 of Vaxart, Inc. of our report dated February 6, 2019, with respect to the consolidated balance sheets of Vaxart, Inc. as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2018, and the related notes (collectively, the consolidated financial statements), which report appears in the December 31, 2018 annual report on Form 10-K of Vaxart, Inc.

Our report dated February 6, 2019 contains an explanatory paragraph that states that the Company has experienced losses and negative cash flows from operations since its inception, has an accumulated deficit, and has debt obligations, which raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

*/s/ KPMG LLP*

San Francisco, California
February 6, 2019

Exhibit 31.1

**CERTIFICATION**

I, Wouter W. Latour, M.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Vaxart, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 6, 2019

By: /s/ WOUTER W. LATOUR, M.D.
**Wouter W. Latour, M.D.**
**President and Chief Executive Officer**
**(Principal Executive Officer and**
**Principal Financial Officer)**

**Exhibit 32.1**

**CERTIFICATION**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), Wouter W. Latour, M.D., President and Chief Executive Officer of Vaxart, Inc. (the "Company"), hereby certifies that, to his knowledge:

(1) The Company's Annual Report on Form 10-K for the period ended December 31, 2018, to which this Certification is attached as Exhibit 32.1 (the "Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: February 6, 2019

By: /s/ WOUTER W. LATOUR, M.D.
**Wouter W. Latour, M.D.**
**President and Chief Executive Officer**
**(Principal Executive Officer and**
**Principal Financial Officer)**

A signed original of this written statement required by Section 906 of 18 U.S.C. § 1350 has been provided to Vaxart, Inc. and will be retained by Vaxart, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.